Friday, 9 October 2020

(10.00 am)

Presentation by MS RICHARDS

MS RICHARDS: Sir, the focus today is on the Oxford Haemophilia Centre, and the time-frame which we'll be looking at is, broadly speaking, the late '60s to the early 1990s.

We will be hearing from Professor Giangrande who took over as director in the early 1990s, in November, and so matters relating to the centre and its work and the treatment of patients under his directorship I will be leaving to his oral evidence.

I've been asked to indicate whether or not Dr Rizza will be giving evidence and the position in relation to that is we don't yet know. So it is possible there may be further hearing days that relate to Oxford.

I should also say that obviously Oxford played a vital role in relation to research and I will be dealing with some documentation and some matters relating to Oxford's research work today, but there is further investigation to be undertaken by the Inquiry in that respect and I anticipate that we will probably produce a written report or analysis of some form or another in due course to be shared with Core

Participants setting out what we've learnt as comprehensively as possible from the documentation about Oxford's research work. So today won't be a full picture of the research but will obviously deal with some of it.

The centre, the Oxford Haemophilia Centre, as well as being a treatment centre, had a research laboratory and a blood plasma fractionation laboratory. That's PFL. It was established as a super regional centre and became the largest haemophilia centre in terms of treatment in the country, treating both adults and children, with a large number of patients coming from outside the area.

SIR BRIAN LANGSTAFF: By "in the country", you mean the UK?

MS RICHARDS: I mean in the UK, yes.

So it occupies a particularly significant role in two respects: one is as a treatment centre it was treating a very significant number of patients, not simply from the Oxford area but patients who were also referred to it from other areas; but, secondly, in particular in relation to the period between 1968 and the early 1990s, under Dr Biggs and then under Dr Rizza, it was obviously a critical time in terms of

the development of haemophilia treatment and the emerging knowledge of the threat of infections and it became the leading centre, as I've indicated, with regards to research into aspects of haemophilia and its treatment and the respective risks of viruses.

Its position in those two respects really makes it unique in a number of ways.

Dr Rizza himself belonged to a range of different committees or working groups and I'll just list a handful of them now. This isn't necessarily an exhaustive list. He was secretary of the Medical Research Council's working party on cryoprecipitate between 1969 and 1979; he was chair of the Medical Research Council's working party to study the use of Factor IX concentrate in conditions other than Christmas disease, 1974 to '80; he was a member of the DHSS expert group on the treatment of haemophilia; he played a key role in UKHCDO; he was what was called secretary or sometimes secretary-general of UKHCDO from 1977 to 1987; he was on or chaired some of the subcommittees or working groups of UKHCDO; he was on a subcommittee on Factor VIII-related activities of the International Committee on Thrombosis and Haemostasis and a member of a task force on the clinical use of Factor IX of the International

Committee on Thrombosis and Haemostasis; he was a medical adviser to The Haemophilia Society; he was a member of the central committee for research and development in blood transfusion, it's not quite clear what the time-frame for that is. His own litigation report suggests that was from 1983. He was a member of the advisory committee on the National Blood Transfusion Service's working group on AIDS, and then he became chair of UKHCDO between 1987 and 1990, chair of its AIDS group between 1987 and 1990; and he was a member of an MRC committee for the epidemiological studies of AIDS, and we'll look at a document relating to that, and part of a working party to study various treatments in relation to HIV.

So, as with Professor Bloom, his influence appears to have extended beyond UKHCDO and beyond Oxford itself.

The Oxford Haemophilia Centre built on earlier work conducted at the Blood Coagulation Research Unit at the Churchill Hospital under the leadership of Dr Macfarlane, but it was established as a haemophilia centre in 1967 under Dr Biggs, Dr Rosemary Biggs, who was director there until 1977, when Dr Charles Rizza took over until his retirement in 1993.

There are some other key personnel at the centre

whose names crop up in the documents: Dr Ethel Bidwell, who was a research scientist and head of the plasma fractionation laboratory; Ms Rosemary Spooner, who occupied a research and administrative role collecting and analysing in particular the annual data returns -- I will deal with this at a later stage of the presentation -- that were submitted or were due to be submitted by all or most haemophilia centres; Dr James Matthews, whose title generally at the centre appears to have been Associate Specialist; Mrs Mary Fletcher, clinical nurse specialist; Dr James Smith, who was the chief project scientist at PFL from 1975 to 1992. Sir, we do have a fairly detailed statement from Dr Smith.

Then Dr Joan Trowell, who was not part of the haemophilia centre but worked at the Radcliffe Infirmary and John Radcliffe Hospital seeing patients with acute and chronic liver disease. We have a statement from her as well. She would attend the centre at the request of Dr Rizza and Dr Matthews to see patients receiving blood products who had developed abnormalities of liver function. She became part of the UKHCDO's Hepatitis Working Party and was involved in some of the research studies undertaken at the centre in relation to liver abnormalities.

One of the key documents that you, sir, will no doubt wish to consider is the litigation report prepared by Dr Rizza in the HIV litigation as an expert witness. It appears to have been the function he was exercising when he prepared it. Its focus is not specific to Oxford, its focus is general, but I will, towards the end of the presentation, draw your attention and the attention of those listening to some parts of his report. It was, of course, prepared at the request of the defendants in that litigation.

If we start by briefly looking at PFL, the laboratory. It was smaller than BPL. It did however supply blood products over a number of years to Oxford and, indeed, to other haemophilia centres and hospitals, and we have examples of correspondence, for example, between Dr Bidwell and the Royal Free or the Queen Elizabeth Hospital in Birmingham in which requests are made for the supply of blood products. It came in particular to specialise in the manufacture and supply of Factor IX concentrate.

If we could go please, Henry, to HSOC0022512, please. This is a 1970 publication authored by Dr Rizza. It's called The Management of Haemophilia and, we're told at the bottom, reprinted from The Practitioner Symposium on Disorders of the Blood,

June 1970.

If we go, please, Henry, to page 9, we can see towards the bottom of the page a heading, "Materials Available for Treatment", and so, as at 1970, Dr Rizza is describing the following therapeutic materials as being presently available for the treatment of haemophiliacs: whole blood, fresh frozen plasma, cryoprecipitate, freeze-dried human anti-haemophilic globulin concentrate, freeze-dried animal anti-haemophilic globulin concentrate.

If we go over the page we can see a little further description of those, so there is a description there of fresh frozen plasma and how it's used. If we can then look at cryoprecipitate, we can see he refers to the work of Dr Judith Pool and her colleagues in the 1960s, and he says this:

"Cryoprecipitate can be prepared by most blood transfusion centres, is a useful source of Factor VIII, and has been used successfully in maintaining haemostasis after major surgery."

He then talks about freeze-dried human AHG and says this:

"Until the introduction of cryoprecipitate, the only concentrated human Factor VIII preparations were the various freeze-dried protein fractions prepared

from human plasma ... always in short supply ... reserved mainly for the treatment of small children or major surgery."

SIR BRIAN LANGSTAFF: I think the central focus of the screen at the moment is above the bit you are reading from.

MS RICHARDS: Oh, it is, could we have the next bit please, Henry. So yes, we've got "Freeze dried human AHG" there described, and then "Animal AHG", and the use of animal AHG had been effectively pioneered under Dr Macfarlane and others in the 50s.

If we go to the next page, please, we see a conclusion there set out here and I'm just going to read it out and make an observation about it. So it says:

"In conclusion it should be stressed again that the successful management of the haemophilic patient requires specialised and individual care based on close collaboration between general practitioner, hospital, haematologists, physicians, surgeons, nursing staff, physiotherapists, social workers, teachers, and indeed everyone who is in any way concerned with the patient's welfare. Since haemophilia is a rare disease this specialised management will not often be provided by the

streamlined service of a general hospital. It is for this reason that the Department of Health and Social Security has designated thirty-six centres in the United Kingdom for the care or treatment of haemophiliac patients. Full use must be made of these centres if the patient is to be treated to his best advantage and prevented from becoming an ill-educated cripple and a burden to himself, to his family and to society."

So those may be observations of their time but it may assist you, sir, and you may wish to read this entire document, in understanding, perhaps, how some haemophiliac clinicians viewed their role at the time, in 1970 and indeed in the late 60s and early 70s in relation to the treatment of individuals with haemophilia.

No doubt in part because of its co-location with the laboratory with the PFL, Oxford made the switch from cryoprecipitate to factor concentrates relatively early compared to some other centres.

Henry, if we could have please PRSE0004645, this is a 1977 article by Dr Rosemary Biggs, but it looks at haemophilia treatment in the UK from 1969 to 1974. We can look at a couple of passages I think.

If we go to page 5, please, Henry bottom half of

the page under the heading, "The Amounts and Types of Therapeutic Material Used", we can see that she says:

"The types of therapeutic materials used at the Centres ..."

So that's looking at centres broadly, to start with:

"... to treat haemophilia A and B patients are set out in Table V."

We will turn on to table V in a moment. She sets out what the materials are:

"... plasma, cryoprecipitate, NHS freeze-dried concentrate and commercial Factor VIII concentrate. Plasma is now little used. Cryoprecipitate is a simple concentrate made from plasma at all Regional Transfusion Centres. Cryoprecipitate is much superior to plasma for the treatment of haemophilia A patients but the material is very variable from one sample to another and the potency cannot be known before it is used."

She explains there's a tendency to use more material for each patient than is probably needed.

"The NHS freeze-dried concentrate is an 'Intermediate Potency' preparation made from pools of plasma derived at present from pools of from 200 to 750 blood donations ... Commercial Factor VIII

concentrate is available from several companies and each batch is derived from 1,000-4,000 litres of plasma collected by plasmapheresis from paid donors. Since about 400 ml of plasma is derived from each donor each batch contains plasma from more than 2500 individual donors. The material is of higher purification than the NHS concentrate."

So this is Dr Biggs' perspective as at 1977 on cryoprecipitate and on the relative pool sizes in relation to NHS concentrate and commercial concentrate.

SIR BRIAN LANGSTAFF: When you say '77, she is reporting on '69 to '74.

MS RICHARDS: She is, and we see a historical overview in relation to Oxford over the page. It's not entirely clear whether her description of pool sizes is based upon her understanding of the overall period or a particular point in time.

If we go to the next page then, please, Henry -- thank you, you are already there -- if we go to the table, first of all, we can see there again the various treatments there set out.

Then if we can go to the last paragraph on this page, please -- sorry, the last two paragraphs on the page. Thank you.

So she then sets out that for haemophilia B, plasma and NHS Factor IX concentrates are the therapeutic materials used and then gives information about Oxford. Returns for the Oxford centre, she explains, are shown separately, and then this:

"It will be seen that at Centres other than Oxford the amount of cryoprecipitate used has increased steadily over the years. This increase has been due to the efforts made by the Regional Transfusion Centres. In 1974 cryoprecipitate still accounted for nearly 80 per cent of all material used. By contrast, at the Oxford Centre cryoprecipitate has never constituted more than 43 per cent of material used and since 1971 the proportion of cryoprecipitate has fallen steadily. In Oxford, plasma previously used to make cryoprecipitate is now fractionated to make ..."

We need to skip over three pages, Henry, till we get to page 10 -- thank you. Top of the page:

"... to make NHS concentrate. The amount of NHS concentrate used in Oxford reflects the close proximity and good co-operation between the Oxford Regional Transfusion Service and the Plasma Fractionation Laboratory which has enabled plasma to be fractionated to make all valuable components rather

than used for cryoprecipitate and red cells alone. The commercial human factor VIII was introduced to the [UK] in 1972 and in 1974 constituted 13 per cent of all factor VIII used in the [UK]."

Then if we skip over the next paragraph to halfway down the page, she says:

"There has been a steady increase in the amount of factor VIII used. As more factor VIII has become available it has been used. There is no doubt that it would be valuable to present all of the NHS factor VIII as a freeze-dried preparation."

So we see there the difference between the usage of cryoprecipitate in other centres and at Oxford, where concentrates were introduced at a much earlier stage.

Towards the bottom of the page, just look at what she says about home therapy here. She states in her view that:

"Cryoprecipitate is much less satisfactory for home therapy than are the freeze-dried preparations. Thus an increase in the number of patients on home therapy is likely substantially to increase the demand for freeze-dried preparations to replace cryoprecipitate. When considering the introduction of patients to home therapy it is usual to give priority

to the most severely affected patients who need most frequent treatment. Thus when home therapy is first used at a Centre the amount of factor VIII used per home therapy patient per annum will be much higher than the average for all patients."

Then she gives an example.

"... the first seven patients who started home therapy in 1971 at Oxford have used 33,400 units of factors VIII per patient per year over the 5 year period from 1971 to 1975. As more mildly affected patients are included in the home therapy programme a fall will occur in the amount of material used per patient. In 1975 54 haemophilia A patients were receiving regular home therapy from Oxford and on average 17,623 units of factor VIII were used per patient."

So, in addition to telling us in this paper the position at Oxford in terms of relative use of cryoprecipitate and concentrates, we can see here that Oxford introduced home therapy at an early stage for a small number of patients, seven patients, in 1971, increasing, by 1975, to 54 haemophilia A patients.

I won't go through the tables that are in the paper, but the calculation that we have undertaken looking at the tables is that during the period 1969

to 1974 at Oxford, the use of cryoprecipitate dropped from 21.99 per cent to 3.86 per cent of total Factor VIII material used. The use of NHS concentrate rose from 45.93 per cent to 60.89 per cent. These are the figures drawn from the various tables in her paper. Commercial Factor VIII was introduced in Oxford in 1973. It made up 17.74 per cent of the product, rising to 35.25 per cent the following year.

The centre didn't use commercial Factor IX product during this period, presumably because of its ability to meet its requirements from Dr Bidwell's work at the PFL.

By 1976, the figures we have in a later paper from Dr Biggs suggest that 42.61 per cent of the material used at the centre was NHS concentrate, 55.85 per cent commercial concentrate -- there appears to have been particular usage of Hyland and Immuno at that point in time -- and just 1.54 per cent cryoprecipitate.

Sir, I will just put the document on screen in relation to that. It's OXUH0003775_080, please, Henry.

So there are two tables. This was a slightly adjusted one following some observations by Dr Bidwell, but this and a similar table from

August 1976 is the source of the statistics that I've just provided.

There is ample evidence in the documentation which we have reviewed of the centre experiencing in the course of the 1970s budgetary pressures and shortages in terms of supply. If we look at OXUH0000673, please, Henry, this is a letter from Dr Rizza dated 18 July 1972. I'm not sure who the Mr Trillwood is to whom it's addressed, but it says this:

"During the past 12 months we've been experiencing increasing difficulties in meeting the needs for AHG for our haemophilic patients. At present we rely entirely upon human cryoprecipitate supplied by Dr Grant of the Regional Blood Transfusion Centre and freeze-dried human AHG concentrates supplied by Dr Bidwell of the PFL supplemented by a small amount of AHG from the Lister Institute ..."

Then he goes on to explain about material received mainly from donors in the Oxford region and then, in the second paragraph says:

"Despite this seemingly excellent supply we are chronically short of material to treat the ever-increasing number of patients that come to Oxford."

If we go to the last sentence of that paragraph:

"About half of the patients treated in Oxford during 1971 from the Oxford region, half were from other parts of the United Kingdom. Until recently the shortage of therapeutic material was unavoidable since no suitable commercial material derived from human blood was available. There are now two sources of supply. One is from Hyland Laboratories and the other is from Immuno AG of Vienna. Both are expensive and it would require material to the value of £2,000 to treat one operation case. Both of these preparations are clinically effective and have been used extensively in other countries. The Immuno concentrate has the advantage of being derived from blood which has been tested and found to be free of hepatitis associated antigen thus diminishing the risk of hepatitis."

That is obviously referring to hepatitis B alone, sir:

"At present, we are often forced to balance the needs of one patient against those of another in allocating treatment. This potentially dangerous practice was reasonable when there was no alternative supply of therapeutic material. We feel now that good material is available commercially, our supply should

be supplemented by the use of this commercially available concentrate. It seems to us quite unethical to continue to withhold treatment from patients where material exists to supply their needs. We therefore ask that the Immuno AG Factor VIII concentrate be bought at an estimated cost of about £15,000 per annum for use at the Oxford Haemophilia Centre. About half the patients for whom this material would be used would come from other regions and most of the material would go to cover patients requiring major surgery."

So we can see there, sir, an early request, July 1972, to be able to use commercial concentrates for the first time in Oxford.

SIR BRIAN LANGSTAFF: The commercial concentrates neither Hemofil nor Kryobulin was at that stage licensed generally in the UK, as I understand it.

MS RICHARDS: As I understand it, sir.

SIR BRIAN LANGSTAFF: My noted dates for the first licensing was 19 February 1973 for Hemofil and 22 March '73 for Kryobulin, so presumably this was on some other basis.

MS RICHARDS: Presumably, sir, yes. I'll check but I don't think the documentation that we have looked at shows clearly the basis upon which it was done but that would seem to follow.

In terms of then -- so that was asking for the money to purchase commercial concentrates. There's then correspondence internal to the Oxford region about funding and we can see an example of it at OXUH0000644 -- sorry, 664 my apologies.

We're now October 1973 and this is a complaint within haematologists -- or within the department of haematology, so this is from a consultant haematologist at the Radcliffe Infirmary at Oxford addressed to Dr Rizza:

"I see from the returns that in the first half of the financial year you spent £23,041 out of the £30,000. How much luck have you had with the DHSS in getting the sum increased? If you have had no joy, perhaps you can advise us where we can cut patient care elsewhere in the hospital to pay the £16,000."

There is a recurrent theme throughout the 1970s of -- I won't go to all the documentation that we've seen -- of representations being made by others within the Oxford area to the haemophilia centre to reduce its spending.

Around this time, October 1973, we can see Dr Biggs writing to the Department of Health and an example is OXUH0000663, so she writes in her capacity as director of the Oxford centre to Dr Waiter at the

Department of Health:

"I'm worried about the supply of commercial Factor VIII concentrate and its allocation to various centres in this country. I had understood that the DHSS planned to buy this concentrate centrally and make allocation to the various haemophilia centres through Dr Maycock's organisation. As I now understand from one commercial firm, the supply of Factor VIII has been left with the firm who have been asked to supply only haemophilia centres."

Then there's reference to there being a minimum order and then she says this:

"At our end we have been told that we can purchase material up to £30,000 annually. This amount is, in fact, far less than our needs. Since it seems that more material is available, it would seem very unreasonable for us to limit our requirements to a pre-determined figure. All of our cases are now more or less emergencies."

She says:

"If the supply is not to be administered centrally I do not feel we can limit our usage to the suggested figure."

Her conservative estimate is at least £50,000 annually as the allocation and she observes this does

not allow for the introduction of new patient to home therapy. So the request being made by Oxford to the department either for a central allocation, centrally funded allocation, or for more money to enable Oxford to purchase more commercial concentrates in 1973.

If we then go please to DHSC0100005_098 there is an exchange of correspondence between Dr Biggs and Dr Maycock at BPL. This is Dr Biggs writing to Dr Maycock enclosing a copy of a letter she sent to Dr Waiter, so another letter that she sent to Dr Waiter:

"The present supply position of Factor VIII is rapidly becoming intolerable. I am not at all sure how the Oxford region will agree to a bill for £100,000-odd for Factor VIII in 1974, only £30,000 being allowing for by the ministry. I am unable to see how we can manage with less despite Dr Bidwell's great efforts on our behalf. We are getting more and more patients and the operation list of haemophilic Factor VIII deficiency stands at 24. It is to me difficult to justify withholding the use of commercial Factor VIII when material is actually in store in this country."

Again, there are a number of representations made at this stage by Dr Biggs and others at Oxford to

say the commercial material is available, allow us to purchase it please and give us the funding so to do.

The response from Dr Maycock is short and to the point, OXUH0000649. He says:

"My personal opinion is that few, if any, disagree with the views expressed in these letters. The unpleasant fact is that there is no cash for NHS and this is borne in upon me almost daily. In fact, as you know the NHS budget has been cut. This impecuniosity seems likely to persist for this financial year at least."

These issues were clearly unresolved at least for Oxford because if we pick matters up in 1977 at OXUH0003761_053, we can see that there is a letter dated 4 July 1977 to Dr Rizza saying this:

"There is once again a good deal of correspondence circulating about your Factor VIII. Everyone is glad for your patients to have the best treatment available. We also know that your centre provides a supra-regional service and that part of the cost of Factor VIII is paid for by a regional allocation. However, times are harder for the NHS and particularly for Oxford than they have ever been."

He refers to underspending. The next paragraph halfway down he says this:

"Of course, there is reluctance to restrict your freedom of use of Factor VIII more than has already been done but I sincerely hope that you will not only keep within the maximal allocation for the year but do everything you possibly can to keep well below it."

Over the page he says:

"The control of expenditure on drugs and allied substances is far from easy and always raises argument about restriction of clinical freedom [that concept again, sir] but I do very much want you to see this matter in perspective."

Then picking it up in the last paragraph:

"I hope that the need for economy, not for the benefit of the Government or the taxpayer but in the trust of other patients, will influence you and that you will reduce the use of Factor VIII from ideal to absolutely essential levels without any further restriction being imposed upon others. No blame lies with you that treatment of haemophilia is expensive but your colleagues cannot avoid expressing some resentment when their legitimate and very often very small needs are refused for lack of funds while your expenditure is so enormous."

So that's the perspective within the Oxford region of the amount of expenditure by the haemophilia

centre and it's instructive to look at Dr Rizza's reply OXUH0003761_052. This give us some insight into practices at the centre, so this is 12 July 1977:

"Dear Dr Cowdell, thank you for your letter of 4th July. We have, of course, been very conscious of the cost of Factor VIII ever since commercial material first became available in 1972 or 1973. We have always striven to restrict its use as far as possible without endangering the patients wellbeing."

Then in the next paragraph, four lines down, he says this:

"We are at present not using Factor VIII at ideal dosage levels because this would entail prophylaxis and we do not feel with the present shortage of money and Factor VIII that this would be right. Practically every dose of Factor VIII that is given to a patient who is actually bleeding at the time or who has undergone dental extraction [and various other surgical operations]. I would like to state that we do not employ prophylaxis at the centre although this form of therapy is employed at some other centres."

He doesn't expressly there deal with the position of home treatment but you will see there, sir, it is being said that treatment is not on

a prophylactic basis. Then there are some observations about wastage. Then over the page second paragraph, he says:

"Finally, there is a bright light on the horizon. Since April 1977 there has been a greatly increased supply of plasma from the Blood Transfusion Centre [that's presumably the Oxford Transfusion Centre] to the plasma fractionation laboratory and we are now beginning to receive nearly twice as much locally made NHS Factor VIII compared to last year. As a consequence of this, we are now, as from this month, able to transfer several of our patients from commercial Factor VIII to NHS Factor VIII and this should lead to a reduction in our expenditure on Factor VIII."

So we see there, sir, that there's been a pattern of clearly considerable usage of commercial Factor VIII but here, as at July 1977, Dr Rizza expressing at least the intention that there should be some reversion to the use of NHS Factor VIII because of the expectation of receiving increased supplies.

The issue of supply had been flagged up by Oxford by that time for a number of years and if we turn to OXUH0003728, please, this is a relatively early Haemophilia Centre Directors meeting. This is

27 October 1972 and insofar as Oxford is concerned, we can see that those present include Dr Bidwell, Dr Biggs, Dr Matthews and Dr Rizza. There were obviously a number of others present including Dr Bloom.

If we go over the page -- sorry, to the third page, Henry, there is a heading "Discussion". I'll just draw your attention to an observation about the use of cryoprecipitate, sir. It's said that apparently at many transfusion centres, confirmed by Dr Maycock, only about half of the cryoprecipitate made was issued for use at the haemophilia centres. It's not clear from this document why that's the case. But it goes on to talk about how the material used at centres merely reflected supply.

If we then go over to page 5 please, Henry, before we come to the discussion about shortages of supply, there's an important discussion about a trial of prophylactic therapy in haemophiliacs. So this is as long ago as 1972. Dr Biggs is describing here the trouble she had had trying to prepare a protocol for a trial of prophylactic therapy and said this:

"She concluded that it would be very difficult to organise a prophylactic trial from a haemophilia centre and that perhaps the only place where it could

be done would be at Lord Mayor Treloar College. She had sent the protocol to Drs Arblaster, Aronstam and Rainsford and they are now planning to organise a trial along lines similar to those in the circulated protocol. Dr Biggs felt it was very important for a trial to be undertaken because we really want to know whether the patients are better having prophylactic therapy or just receiving treatment on demand. There were sharp differences between these two modes of treatment. On-demand treatment means giving treatment at home or at hospital whenever a bleed occurs. Prophylaxis involves treatment at regular intervals, regardless of whether or not bleeding occurs. The directors were invited to support the conduct of this trial at Treloars."

Obviously, we will come back to look at these issues in more detail when we look more carefully at Treloars in March of next year. But over the page the discussion continues about placebo groups and the material to be used.

If we pick that up halfway down the page, the choice of material is referred to and the conclusion was that a freeze-dried concentrate should be used. Drs Arblaster and Aronstam had decided to use the Immuno material from Vienna if possible and applied to

the Department of Health for money to buy the material. There's then a discussion about Hyland and Drs Maycock and Bidwell thought they could supply enough material were they asked.

Then we have this information from Dr Biggs as director of Oxford:

"Dr Biggs said she had felt that any material which could be made in England was too urgently needed for treatment of serious bleeding for it to be allocated to a clinical trial of prophylactic therapy."

So again a reflection, perhaps, of the concern about shortage of supply but the upshot appears to be the proposal is for the use of these early commercial concentrates to be used at Treloar in the trial of prophylactic therapy. As I say, we will come back to that in more detail when we look at Treloar.

If we go over the page please to page 8, Henry, we then have a discussion about home treatment. There's a reference to Dr Britten's film on home treatment. Then we see the policy at Oxford:

"Dr Matthews outlined the policy at Oxford using freeze-dried concentrate and Dr Dormandy at the Royal Free hospital using cryoprecipitate."

Sir, you have already heard on a number of

occasions that Dr Dormandy seems effectively to have pioneered in particular the use of cryoprecipitate -- not pioneered but was a strong supporter of the use of cryoprecipitate for home therapy at the Royal Free in the 1970s, but clearly here, even as at 1972, Oxford is using concentrate for its home therapy programme.

Then you will see reference to supply:

"It was stated that the supply position in some areas was so poor that directors could not allow any material to be kept in patients' homes as this policy would deplete stocks."

Then if we go to the next page under the heading "Supplies of therapeutic material", there's then a discussion about the issue of supply and demand:

"Dr Biggs described a recent attempt she had been making to assess the amount of Factor VIII likely to be needed. This showed that freeze-dried concentrate was unlikely to be more wasteful of plasma than cryoprecipitate. The amount needed was dependent on the number of patients in the country and the amount required per patient. The conclusion was that we were likely to need freeze-dried material from 250,000 donors units annually and the total material required was likely to be of the order offered 500,000 donor units annually. The desirability of increasing

home treatment and the availability of good commercial material make the question of increased British supply very urgent."

That's further discussed over the page. If we pick it up halfway down the page, it's said there:

"Two main topics were discussed. One concerned the purchase of commercially available Factor VIII preparations, the other was the more long-term problem of increasing the supply of a good quality soluble British product."

So the issue there of self-sufficiency:

"Many directors were pressing for permission to purchase the good commercial product manufactured overseas."

Then there's agreement that the chair will ask the Department, or the Ministry of Health and Social Security as it's here referred to, to set up an expert committee to consider and advise on the supply of Factor VIII, taking into consideration the fact that directors prefer freeze-dried Factor VIII to cryoprecipitate.

That was early 19 -- that was early in the 1970s, in October 1972. We see a little more about the home treatment programme and the materials at Oxford from a later document.

If we go please to RLIT0000022, Henry. This is a much later document, sir. This is what is described as a witness seminar held at the Wellcome Institute in February 1998.

If we go on to page 12, Henry, we can see who was present and for today's purposes I draw attention to the fact that Dr James Matthews and Dr Charles Rizza were both present at that seminar.

Then if we go please to page 43, Henry, there's a discussion here that again just gives some insight into how things were done at Oxford in the early years. So this is Dr James Matthews talking. He's talking, first of all, about his experience with transfusion equipment in or before the 1960s. If we go then to the bottom of the paragraph, it refers to:

"When dealing with bleeding patients in the early days one of the main problems was shortage of treatment material."

Then he discusses fresh frozen plasma and Dr Jean Grant's role as Director of the Blood Transfusion Service in Oxford. He describes:

"... a time when clinicians at the haemophilia centre had access to the key of the Blood Transfusion Centre and could obtain plasma out-of-hours without delay. Plasma was used for the treatment of many of

the common bleeding episodes which responded to the limited factor level achievable with the material."

Then if we could just see the whole page, Henry, we can see a question is then asked by Professor Lee:

"Was it right to think that cryoprecipitate was a thing that really pushed home treatment?"

Dr Matthews responds:

"It did make a big difference, because it was easily made. It still wasn't the ideal material because it was a liquid plasma product stored in the frozen state but many centres found it a very useful material for home treatment."

Then Professor Lee describes what was done at the Royal Free (and we'll ask Professor Lee about that herself in a couple of weeks) but then, towards the bottom of the page, Dr Rizza talks about Katharine Dormandy, Dr Dormandy of the Royal Free, one of the few to start using cryoprecipitate for home therapy and he refers to a discussion about people having to have freezers at home.

Then if we go to the next page, we see Dr Matthews' contribution about the position in Oxford:

"I think it's probably fair to say that we used the freeze-dried pool plasma concentrate in preference

because it was available to us and seemed a suitable material for home treatment."

That's the Oxford perspective on home treatment and the products that were being used. As we saw from that earlier document by Dr Biggs, we know that home treatment began in Oxford in 1971 and was fairly rapidly increasing, so that by 1975 about 25 per cent of Oxford's haemophilia A patients were receiving home treatment.

If we go to OXUH0000917_002, we can see that there was in June of 1975 a home treatment trial being undertaken at Oxford and a trial at St Thomas'. This is a letter from Dr Rizza to Dr Bidwell at the PFL. It appears that Dr Rizza's been discussing matters with Professor Ingram. Those who were listening yesterday will recall Professor Ingram was then director of St Thomas'. Agreement had been reached that for this particular home treatment trial -- and it's not clear from this what the parameters of that trial was -- Oxford would use material prepared by Dr Bidwell and St Thomas' would use Elstree BPL product.

We know, I think from other documents, that commercial concentrates were being used in home treatment. In fact, I'll just look at one to show you

that, sir. It's OXUH0003775_005. This is a table of usage between January and June of 1976. We can see under the heading "Units of Factor VIII issued for HT", so that's home treatment, although the largest amount is NHS concentrate and there is no cryoprecipitate being used for home treatment, both Hyland and then a small amount of Immuno product has been issued for home treatment in that six-month period.

If we could then please go to OXUH0003761_036, please, Henry. This is a May 1977 letter from Dr Rizza to a doctor in Jersey, who has obviously written to Oxford asking for some guidance on the best commercial Factor VIII concentrate to buy, and Dr Rizza says this:

"The Factor VIII concentrates available commercially in this country at present are as follows: Hemofil made by Travenol, Kryobulin made by Imunin, Profilate made by Abbot, Factorate made by Armour, Koate made by Speywood."

Sir, pausing there, it was entirely rightly pointed out to us on our written presentation that we'd spelt Profilate wrong and I just wanted to make the point what we had spelt was Dr Rizza's spelling in the letter, not our own spelling error. It was also

pointed out to us that Koate is not made by Speywood. That's absolutely right but that's what Dr Rizza in this letter is describing and we know it was being distributed by Speywood.

SIR BRIAN LANGSTAFF: To say these were made by these particular corporate entities at Thetford, Dunton Green and so on, that's plainly wrong.

MS RICHARDS: Absolutely.

SIR BRIAN LANGSTAFF: To read it that way. The addresses are given because that's where presumably you'd expect the intending purchaser to write because they are the agents.

MS RICHARDS: Yes, they are the United Kingdom-based agents. Then, in any event, we go on to see what Dr Rizza says about the usage of these materials at Oxford:

"We have used all 5 preparations and we find them all equally effective clinically. There is very little difference with regard to price, they all run at about 8p per unit of factor VIII activity, although I believe you can negotiate for a lower price with Speywood Laboratories Ltd for Koate.

"We tend to use Hemofil which comes in ampoules containing 250-300 units [et cetera]. The next choice I think is Factorate which again comes in ampoules

containing 250-300 units. Our third choice is Kryobulin but my feeling here is that it occasionally is slightly more insoluble than the others and can therefore be a nuisance if you are in a hurry. I would therefore recommend to you Hemofil or Factorate as your first choice."

So, sir, that gives us some guide to the fact that all of these commercial products were in usage in Oxford at the time and it's apparent that Dr Rizza's preference there appears to be Hemofil and second choice Factorate.

Just in terms of Oxford's policies towards use of blood products, can I ask to put up on screen COLL0000001, please, Henry. Could we go to 0000002.

So this is a letter that was sent in relation to a particular patient -- it's been redacted -- in response to a letter that had been written by the patient's family to Dr Rizza, and this is Dr Rizza's response. It just gives us some insight -- this is December 1984 but he is talking about usage certainly as least as far back as 1980 then is concerned:

"Thank you for your recent letter concerning [X's] treatment, the type of Factor VIII he is receiving and the problem of AIDS. I have looked back over our records and find that [X] received NHS

Factor VIII until June, 1980 when he was given American concentrate for the first time. Thereafter he received NHS concentrate again until March, 1981 when he was changed from NHS to American concentrate and has continued to receive American concentrate since then."

So we see there the particular switch between American and NHS for that patient, and then this more general observation:

"The NHS Factor VIII concentrate is in very short supply and we have always, as far as possible, reserved it for young children and adolescents. Ultimately most severe affected patients are changed from NHS to commercial Factor VIII especially those who use larger amounts of Factor VIII."

Then he goes on to talk about issues of risk. Then we see, picking it up in the last part of that next paragraph -- sorry, the paragraph above, Henry, my apologies.

It is suggested:

"I am sure [that the patient] has not so far received as much commercial concentrate as he would have done had he been receiving equal amounts of NHS and commercial concentrate since 1972 (when commercial concentrate first came in)."

So again, sir, that reference to 1972, as we have seen from earlier correspondence. But the broader picture that emerges from this letter is Dr Rizza's account that Oxford's policy, due to shortages of supply, had been, it's said, always as far as possible to reserve Factor VIII concentrate for young children and adolescents and then switch on to commercial concentrates.

The reason for that policy is not spelt out but obviously one reason may have been the perception that NHS concentrate was safer because of the relative pool sizes, but that's not articulated in terms in the letter.

SIR BRIAN LANGSTAFF: And possibly the type of donor.

MS RICHARDS: Possibly. Oh, yes. Yes, sir, that's true.

More broadly in terms of the national picture on self-sufficiency, Dr Biggs was an early and strenuous advocate for self-sufficiency and we can see that from DHSC0100025_062. We've seen the observation she had made at that meeting, Haemophilia Centre Directors meeting, in 1972. This is five years earlier, in 1967, when Dr Biggs is writing from the Oxford Haemophilia Centre to Dr Godber at the Ministry of Health (I think the then CMO):

"I would like to take this opportunity [she says

in paragraph 2] to mention the question of preparations for the treatment of haemophilia and Christmas disease. These are mainly human blood products."

She says:

"The preparations I have in mind are concentrates from human plasma of factors VIII and IX ... both of these preparations are in very short supply in England and at present they are also scarce everywhere else in the world. They are so important for the treatment of these patients that their use makes the difference between life and death in many cases and the difference between quick recovery and long-drawn, painful illness with residual crippling in many others. At present, many haemophilic patients are not aware of the great efficacy of this treatment and do not attend as they should for treatment."

Then she says this:

"I have estimated on the basis of our practice that a minimum quantity of these concentrates required at present is the product from about 50,000 donors a year."

She then goes on to talk about the supply of material, and then says this:

"The shortage of material to treat these

patients is not new but at the meeting that I attended recently, the plans made by the United States to deal with the shortage were outlined. I have good reason to believe that within the next year or two, very large amounts of these products will become available on a commercial basis in the United States. I estimate that the product from more than a million donors a year will be processed. When this material comes on to the market, we shall be obliged to buy it at a very high cost for our patients unless the English shortage can be remedied."

So as at August 1967, she is predicting that there will be commercial concentrates and there will be a pressure to buy them, unless something is done to ensure that there is sufficient NHS concentrate. Then she says this:

"In this country, we have pioneered this treatment. We have the personnel who know how to make the products. We could easily have enough plasma to serve as starting material. It would seem to me a great pity if we cannot make our own material in this country for lack of the organisation, apparatus and buildings in which to work. The purchase of the finalised products in the United States will undoubtedly be very costly. A part of the

United States product will be made on contract by the American Red Cross and will presumably not be available for sale abroad, but a large amount will be made by commercial enterprise and on sale", and she gives an estimate of cost.

"Surely it would be less costly to us to do everything to expedite the manufacture of these fractions in England and, in particular, to accelerate as much as possible the new fractionation buildings at Elstree and in Edinburgh. I feel that it is perhaps time to try to reassess the quantities of these products that might be needed and to try and work out an emergency plan to try and meet the need."

In 1967 that is her call, effectively, for steps to be taken to achieve self-sufficiency; otherwise, she predicts, as we know entirely correctly, both as far as Oxford's concerned and nationally, that Haemophilia Centre Directors will seek to purchase and use commercial materials.

SIR BRIAN LANGSTAFF: The evidence of Dr David Owen , when he gave evidence a few days ago, was that this letter was written by someone who would deserve great respect and it was, I think, partly the basis for his, albeit retrospective, conclusion that more should have been done at an earlier stage to achieve self-sufficiency.

MS RICHARDS: Yes, and I'll come on after the break, sir, just to look at a small number of documents from the 1970s which show the interactions between Oxford professionals (mainly Dr Biggs and Dr Rizza, I think) and the Department of Health on this issue. But, sir, that is a correct reflection of the evidence that Lord Owen gave orally to us.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Sir, is that a convenient point at which to take the break?

SIR BRIAN LANGSTAFF: Yes, it is. Shall we come back at 11.35.

(11.04 am)

(A short break)

MS RICHARDS: Sir, we had been looking at Dr Biggs letter from 1967. We have already looked at the discussion that then took place of shortages of supply and the need to increase British supply at the Haemophilia Centre Directors meeting in 1972. You may recall a decision was taken that the then chair, Dr Blackburn, or Professor Blackburn, would write to the department about the issue. We can see that leads to the establishment of an expert group involving Dr Biggs and Dr Rizza.

If I can pick it up with Professor Blackburn's

letter.

Henry, it's BPLL0008096_002, please.

12 December 1972, Professor Blackburn wrote to Sir George Godber, the Chief Medical Officer, in these terms:

"I am taking the liberty of writing to you in my capacity as Chairman of the Haemophilia Centre Directors of the [UK]."

Then he refers to the meeting that we looked at a little while ago this morning, in October 1972:

"... I was instructed to write to you asking if the Department of Health ... would set up an expert committee to consider the supply of therapeutic materials ..."

Then he goes on to say:

"The most effective materials available for the treatment of haemophilic patients are:

"(1) Cryoprecipitate.

"(2) Freeze-dried Factor VIII concentrate.

"The cryoprecipitate is made at the Regional Blood Transfusion Centres, and the quality and amounts of this material vary from one region to another. The freeze-dried material is made at the [BPL] at Elstree, at Oxford and at Edinburgh.

"The Haemophilia Centre Directors would prefer

always to use the freeze-dried product, but only about one-tenth of the required material is at present available in this form. The supply of cryoprecipitate is very variable. The directors of thirteen centres state the supply is adequate, while the directors of seventeen centres state that their supply is inadequate.

"The great shortage of materials is limiting the treatment that can be performed, particularly the introduction of Home Treatment."

Then he refers to the commercial products:

"Recently, the Hyland Laboratories (USA) and the Immuno Laboratories, Austria, have produced preparations or human concentrate. These commercial concentrates are effective and satisfactory to use, but both are more expensive per unit than the present cost of the British concentrate.

"The Directors feel that there is an urgent need to increase supplies of Factor VIII Concentrate, in particular of the freeze-dried concentrate. Many feel that if a British preparation cannot be made available very shortly, the commercial preparations should be bought."

So that was the UKHCDO's letter to the Chief Medical Officer. If we then look at CBLA0000135,

please, we can see this is an internal department minute, dated 20 February 1973, and the proposal is:

"I think we must go ahead as rapidly as possible with assembling an expert group to advise on future requirements for the treatment of haemophilia as suggested in Dr Maycock's minute of 7 February. Sir Philip Rogers is concerned about the possible financial consequences and is anxious that these should be quantified as soon as possible bearing in mind the scope for meeting blood product requirements from home sources."

So there's a proposal to have an expert group. There are further documents, which I don't think we need to look at in relation to it, some of which we explored with Lord Owen, which set out an aim to achieve a degree of self-sufficiency.

Then in terms of the group itself, we find the minutes of its first meeting at PRSE0004706.

We can see it's the "Expert group on the treatment of haemophilia", meeting on 20 March 1973, and relevant in particular for today's purposes we have Dr Rosemary Biggs and Dr Rizza both present. So both there representing Oxford as the largest treatment centre, and essentially influencing or seeking to influence Central Government policy in that

respect.

Set out below the list of attendees is the advance in the development of human freeze-dried concentrate. Then we see in the next paragraph product licences have now, by this time, been granted to two firms importing the freeze-dried concentrate from overseas.

We can see that there is a paper that was presented by Dr Biggs and then a paper presented by Dr Maycock and then there is a discussion.

We can go over the page. We don't need for present purposes to look at all of it but there's a comparison of the merits of cryoprecipitate and of freeze-dried concentrate.

And just look at the very bottom of that page:

"A possible disadvantage ..."

This is in relation to concentrate:

"... arises from the fact that AHG concentrate is prepared from a larger pool of donations, and in theory therefore, the risk of hepatitis is greater. About 1 in 800 of the donors who present to the transfusion service is a carrier of hepatitis B antigen."

So a recognition there of the potential relevance in terms of hepatitis risk of comparative

pool sizes. Top of the next page talks about the present policy of rejecting donations that test positive for hepatitis B. Then it is said that:

"In practice, studies in several centres have shown that the incidence of hepatitis among severely affected patients who have been treated with the freeze-dried preparation is not very much higher than that at centres not using freeze-dried concentrate ..."

That I think is based upon the paper that was presented to the committee by Dr Biggs. It may, however, be a reflection of the fact that the comparison as at that stage was not between cryoprecipitate and very large pool concentrates but between cryoprecipitate and NHS concentrate manufactured using, at that stage, much smaller pools.

SIR BRIAN LANGSTAFF: Yes, if the pool size was 250 to 750, as recalled in '76/'77, then it would have been at least no bigger at this stage.

MS RICHARDS: Yes, and then we can just see the recommendations of the expert group, so the recommendations including that of Dr Rizza and Dr Biggs, is, amongst other things, for the DHSS to give early consideration to central purchase of concentrate from the two firms. So the expert group

is here urging an ability to purchase commercial concentrate. Then at (3) we can see an aim of self-sufficiency and, obviously, that was an issue then explored in part with Lord Owen.

SIR BRIAN LANGSTAFF: Could we just go back to the previous page for a moment because my eye was just caught by something as you flicked over. Back again. There was a reference to the number of reactions to cryoprecipitate which -- I'm not sure if I've got it here or overleaf.

Could you go overleaf to page 3, please, Henry. Thank you.

Yes, it's the second paragraph.

MS RICHARDS: "A survey quoted by Dr Biggs indicates that the incidence of anti-Factor VIII antibodies in about 6 per cent of patients does not seem to be related to the type of therapeutic material used."

SIR BRIAN LANGSTAFF: The reason why I was interested in that is that quotes 6 per cent and what we were quoted by Dr Colvin was about -- somewhere between 15 and 20 per cent, wasn't it?

MS RICHARDS: Yes. I think this is based upon a paper from Dr Biggs. Let me just see if that's right. I don't think we have the precise paper or I don't have a reference to hand.

SIR BRIAN LANGSTAFF: We can look at it later but it looks as though there may be different estimates of how much reactivity there was in different products which were used.

MS RICHARDS: We do have a paper, which I will come on to in a few minutes, from Dr Biggs at around this time which was for the Medical Research Council's Blood Transfusion Research Committee working party. So there's a multiplicity of committees and it's quite difficult to distinguish them in one's mind. We'll look at that in a few minutes. It may be that will have similar information, I'm not sure.

In fact, I think we can probably look at it now, Henry, PRSE0002350.

We see this is authored by Dr Biggs and Dr Rizza and a number of others on behalf of the "[MRC's] Blood Transfusion Research Committee Working Party on the Cryoprecipitate Method of Preparing AHF Concentrates". It is one of a number of papers authored or co-authored by Dr Biggs and sometimes Dr Rizza at this time.

If we go to the next page you'll see that the purpose of this paper -- I'm trying to see if we've got the date of it. I don't think we do. But it's about 1973. Six lines down:

"The present communication is an attempt to assess the advantages and disadvantages of various therapeutic materials containing Factor VIII activity and to estimate the ... amount likely to be needed in this country each year."

Then if we skip down a few further lines, she says:

"The supply of Factor VIII concentrate in the form of cryoprecipitate has greatly increased in recent years and this preparation has revolutionised the treatment of patients with haemophilia. The provision of cryoprecipitate at the present level of production has involved a major effort on the part of the transfusion centres."

Then if we go to the next page, picking it up in the second paragraph, halfway through, she says there is no problem with the supply of Factor IX concentrate, and then says:

"The situation is quite different in the case of factor VIII where more than half of the Directors of the 42 Haemophilia Centres consider that the present supply of factor VIII concentrate is inadequate."

There's then data about the number of haemophilia patients. Then if we go on to page -- it's at page number 5 at the top of the page, Henry,

but it's probably -- the next page, please, Henry.

There's a section of the report then headed "Comparison of freeze-dried concentrate and cryoprecipitate", and she or they talk, about five lines down into that paragraph:

"The preponderance of cryoprecipitate is due to the fact that this preparation can be made at all Transfusion Centres."

Then she says:

"From a long-term point of view cryoprecipitate is not necessarily the best preparation for treatment."

Then if we go on to page 9, Henry, there's a heading, "Convenience of Manufacture and Convenience and Safety in Use":

"Cryoprecipitate is easier to produce than freeze-dried concentrate if small amounts of concentrate are required. On a large scale the manipulation, storage and reconstitution of thousands of single bags of cryoprecipitate may be much less satisfactory than a co-ordinated large scale fractionation ..."

Then there are various discussions about the process. Over the page, and this is really relevant to the extent of giving us a view of the organisation

for the production of cryoprecipitate in 1972/3, second paragraph:

"The procedure for making up cryoprecipitate for administration to patients varies very much from one centre to another", and she draws a distinction between the Blood Transfusion Service and haemophilia centre staff and then ordinary hospitals where it may be more problematic.

Then she talks about freeze-dried concentrates on the next page. If we go to page 12, Henry, we get complications of treatment. Picking it up third line down:

"Freeze-dried concentrate was made from pools of plasma derived from about 200 donors."

So small pools by later standards:

"A pool of plasma derived from many donors has a predictably greater chance of containing the hepatitis virus than plasma from a single donation. There is always theoretically a greater chance of a patient contracting hepatitis if treated with a freeze-dried preparation than if plasma or cryoprecipitate are used."

Then the suggestion a few lines down is the frequency of hepatitis didn't seem to increase very greatly. That's in reference to a '74 publication, so

this might be later than '74, in fact.

SIR BRIAN LANGSTAFF: That comment bears out your comment about what the comparison was.

MS RICHARDS: Yes. I'm trying to see, sir, whether this paper deals with the point about inhibitors but it doesn't at the moment seem to. It deals with costs, it deals with amounts, I'm not sure it goes back to the point you were asking about. It deals with home treatment on page 18, prophylactic treatment. No. It might be worth just going to page 21, though, for the conclusions, at point 2:

"Comparisons of cryoprecipitate and freeze-dried concentrate made in Oxford suggest that from the point of view of conservation of the Factor VIII activity of the donor plasma and of recovery of infused activity in the patient the two preparations are equally efficient."

So that might go to another of the points that was made by Dr Colvin:

"It should be noted that the Oxford cryoprecipitate is among the best cryoprecipitate preparations tested."

Then it goes again to talk about difficulties of preparation, and over the page there's a recommendation that concentrate is the therapeutic

material of choice for home treatment. Perhaps just looking at point 5 on that page:

"The number of donations contributing to pools of plasma used to make concentrates does affect the probability that a particular pool may contain hepatitis virus."

Then there's a discussion about the impact or likely impact of universal screening for hepatitis B. But no I don't think this paper does, in fact, go back to the issue you were asking about.

SIR BRIAN LANGSTAFF: It does say at the very last sentence there:

"The incidence of anti-Factor VIII antibodies is not affected by the type of human material used to treat the patients."

So at that stage anyway, using those preparations as they were at that time, there doesn't seem to have been any significant difference.

MS RICHARDS: No.

SIR BRIAN LANGSTAFF: That's not I think a reflection of what has been said since about cryoprecipitate and its greater likelihood of causing intermittent reaction but perhaps we can look into that at a later stage. I've taken you off course.

MS RICHARDS: That's no problem, sir.

Just sticking with then developments 1973/1974 if we go to CBLA0000206, this is again one of a number of communications between Dr Biggs and Dr Waiter at the department. This is May 1974 and we can see Dr Biggs' perspective of the appropriate policy to adopt in relation to the use of commercial product. In the third paragraph:

"I feel that the commercial human Factor VIII should be made available to doctors who treat haemophilic patients as an interim measure until enough can be made in this country by the NHS. I am not in favour of any preferential use of commercial Factor VIII and feel that the NHS could well provide its own in absolutely adequate amounts, if only a little money or effort could go into the fractionation laboratories."

So very much six years on she is making the same observation -- seven years on -- that she had made in 1967 to the Department and she, as she mentions there, writes a letter to The Lancet which we have at PRSE0002515. We looked yesterday, when considering St Thomas', at a response that Professor Ingram had written to this letter agreeing with it. This is the original letter from 1974 published by Dr Biggs -- published by The Lancet from Dr Biggs, "Supply of

blood clotting Factor VIII for treatment of haemophilia".

We can pick it up in the right-hand column:

"The question that arises is for how long should this shortage of Factor VIII be considered to be a reasonable feature of haemophilia treatment? Two things, in my view, make continued limitation both unnecessary and unethical. The first of these is the fact that three commercial companies are now licensed [so that's the development of a third company now] to sell good-quality human Factor VIII in this country and they have between them amounts of material adequate to supplement the present provision of the NHS. In fact, at the time of writing one commercial firm has over 1 million units of Factor VIII awaiting use. The second consideration which renders adequate provision of Factor VIII both feasible and desirable", and then she refers then to the ability to use plastic containers and then this:

"The blood donated in the UK is freely given by responsible citizens; the best use of this valuable resource clearly lies in the best use of all parts of the blood."

She then poses the rhetorical question:

"Why then is there still a chronic shortage of

Factor VIII in the clinics where patients are treated. The reason is that Factor VIII is expensive, whether bought commercially or made by the NHS. Over the country as a whole a supply of commercial human Factor VIII sufficient adequately to supplement that made at present by the NHS would cost an annual 1 to 2 million. It is claimed that a sum of money of this order cannot be found from current allocations to the NHS without reducing money spent on the other necessities."

Then she talks about the pros and cons of financial arguments and how in the long run it would probably be cheaper to pay for agreement than pay for the consequences of undertreatment. Then there is a call at the very bottom of the letter for:

"... an immediate solution to the ridiculous impasse of large available stocks of therapeutic materials locked up in stores because no-one will buy them and on the same time patients in dire need of this same material."

We see, I won't take you through the further documents, sir, at this stage, but there are then letters we see for example in 1976, two years further on, from Dr Rizza making exactly the same point. He observes to a colleague at the Queen Elizabeth

Hospital:

"I'm sure it will be some time, probably years, before the output of NHS concentrates meets the requirements of the haemophilia centres of the UK", and then Dr Rizza adds this:

"Until that time, I think it will be necessary to continue buying the commercial Factor VIII."

That then, as we know, is reflected in what was actually done by Oxford in relation to its patients.

Just before I leave the topic of self-sufficiency and shortages of supplies, you may recall, sir, from the presentation in relation to Professor Bloom that a point came in 1980 when Dr Rizza and Professor Bloom wrote to the Secretary of State for Health.

We'll just look at that now. It's HCDO0000394_049. It's a letter from Professor Bloom and Dr Rizza dated 12 November 1980 to the Right Honourable Patrick Jenkin. We don't need to go through all of it but we see again the concern expressed in the first paragraph, it is said, by Haemophilia Centre Directors that the shortfall of concentrates provided by NHS manufacturers for the treatment of haemophilia and at the consequent need to purchase large quantities of Factor VIII from foreign

commercial sources.

If we go over the page, what's said in the opinion of Dr Rizza and Professor Bloom is that the problem should be solved by improving NHS transfusion sources within the UK both centrally at the fractionation laboratories and peripherally at blood transfusion centres.

The response, sir, I won't go to it now but you will notice 18 December 1980 from Sir George Young. Part of the issue at the time was the potential commercial takeover of BPL. He deals with that and says that's not going to happen but also says, well, we're going to spend more money on BPL.

So we see there both the fact that commercial products were in considerable use at Oxford throughout the 1970s and indeed the first part of the 1980s and the stated reason for that emerges from the documents as really being twofold. One is a belief that Factor VIII concentrates are the best form of treatment for haemophilia A, and the second aspect to it is the view that in the absence of NHS factor concentrate commercial concentrates would need to be used to supply the shortfall.

We've seen already from some of the materials a clear knowledge of the risks of hepatitis.

Unsurprisingly, given Dr Biggs' and Dr Rizza's roles at Oxford and within UKHCDO, they were regular I think invariable attenders at the meetings of the Reference Centre Directors and at the meetings of the centre directors as a whole, and in receipt of the regular reports from Dr Craske for the Hepatitis Working Party or before it's institution in I think 1977, ample evidence of general discussions of hepatitis year in, year out.

There are again unsurprisingly in the documents frequent reference in the course of the late 1960s and throughout the 1970s to patients showing signs of jaundice, to monitoring for hepatitis.

If we go to HCDO0000581, we can see here a specific study in which Dr Biggs and Dr Rizza were involved on two aspects of the complications of treatment. One is antibodies but the first is jaundice. This is a publication in 1974 and we can see a study being made of the incidence of jaundice and of antibodies during 1969 to 1971 based upon an analysis of data and records received in relation to patients.

We know also from documentation we've seen that Oxford participated in a number of studies at this time. There were specific studies -- a specific study

relating to Hemofil and I'll come on to some of the research studies at a later stage today.

There is little that we have found in the contemporaneous documentation to show particular consideration being given to non-A, non-B hepatitis as an emerging issue in the course of the 1970s and the documents which we've looked at, if we leave aside the UKHCDO meetings, do not record any particular awareness one way or another of the severity or potential long-term sequelae of non-A, non-B hepatitis. We do get some insight into Dr Rizza's position in relation to that in his litigation report, and so I'll come to that towards the end of the presentation to show what Dr Rizza says in his litigation report about knowledge of non-A, non-B hepatitis and its seriousness.

The material we've seen really talks in the first half of the '70s perhaps unsurprisingly about hepatitis in general terms, there are specific studies looking then in relation to issues concerning hepatitis B. There are documents that refer to ongoing monitoring of liver function tests and observation of abnormalities in liver function tests and the like.

We know, for example, that in the mid-70s

Dr Rizza was involved in designing an early prospective hepatitis study in conjunction with Treloars. So hepatitis and the risks of hepatitis were clearly a focal part of the work of Oxford in the course of the 1970s. That particular Treloars study we will return to when we look at Treloars in more detail next year.

We can see, if we go back please, Henry, to PRSE0004645, this is the report we looked at earlier, sir, about haemophilia treatment in the UK from '69 to '74 by Dr Biggs and if we go to page 11, Henry, we can see in the penultimate paragraph, sir, towards the bottom of the page beginning "In 1972", we can see this observation about pool sizes and comparative risks of hepatitis:

"In 1972 the commercial human Factor VIII was used for the first time in the UK. This material is made from very large pools of plasma collected from paid donors, some of whom have lived in poor districts of the US cities and the similar situations of other countries. It has been shown that such commercial blood has been ten times more likely to transmit hepatitis than blood collected from unpaid donors by national transfusion services."

The reference there is to Maycock 1972. Then

she talks about the introduction of commercial Factor VIII. So there is a record there of Dr Biggs and presumably, therefore, Dr Rizza's understanding in terms of the risk of hepatitis, of the relative risks from NHS and commercial Factor VIII reflecting pool sizes and nature of donors.

Insofar as the developing knowledge of the risk of AIDS is concerned, the documents don't show when Dr Rizza or his colleagues at Oxford first knew of the possibility of an association between blood products and AIDS but we know that the matter must have come to his attention by the time of the Reference Centre Director meeting on 6 September 1982 and you will recall, sir, we've looked at it on a number of occasions, that's a meeting Dr Rizza was present at which Professor Bloom is recorded as asking Dr Craske for information about AIDS and its possible relationship with blood products. Dr Craske said he'll find out more and have some more information available and then we have the later meeting that month where the reference is made to there being a remote possibility of a connection.

However, alongside what we see from the Haemophilia Centre Directors meetings, we do have some other material from Dr Rizza -- relating to Dr Rizza's

knowledge. So if we start with OXUH0001617_001, please. So this is 8 October 1982, shortly after those two UKHCDO meetings in September, and it's a letter from Dr Rizza to Dr Craske. The subject of the letter is a study in relation to the incidence of acute and chronic hepatitis but we can pick it up in the second paragraph where the issue of AIDS is raised:

"With regard to the acquired immune deficiency state in haemophiliacs I discussed this with Helen Chappell who is the Consultant Immunologist here and she was very interested in the problem and would be quite interested in being involved in any study of our patients.

"Shortly after you 'phoned me last week I received a telephone call from a physician in the States asking what our experience in this country was. He had just been to a meeting where the 3 cases of haemophilia with AIDS already publicised were discussed, along with another one or two possible cases presented at the meeting. Apparently the whole problem has caused quite a stir in the haemophilia world in the States so much so that one very senior physician has withdrawn his factor VIII concentrates from the accident room and insists on vetting the

patients himself before any dose is given. I feel the whole thing should be looked at urgently if only to clear the air and dispel some of the apprehension that has been stirred up."

So that gives us an insight into the information available to Dr Rizza as at October 1982, about perspectives in America and his own response, including a feeling that the matter should be looked at urgently.

Again, Dr Rizza looks at this issue in his litigation report retrospectively, and I'll come back to that.

We know then that Dr Rizza, attended a meeting of the UKHCDO's Hepatitis Working Party on 19 January. We will perhaps look at that, please, Henry. It's HCDO000558.

This is 19 January 1983. If we go to page -- we can see Dr Rizza's there, Dr Craske's there and Dr Trowell from Oxford is there, Miss Spooner is there, Mrs Fletcher. So Oxford very well represented on the Hepatitis Working Party.

If we go on page 3 it should be. Yes, halfway down the page:

"Acquired Immune Deficiency Syndrome (AIDS)

"Dr Craske reviewed the developments in the

field ... At Dr Kernoff's suggestion, he had written to Dr Lawrence at ... (CDC), Atlanta ..."

Then we can see Dr Craske is reporting ten cases of AIDS in haemophilia A patients who have none of any other predisposing causes:

"All except one ... were patients with severe coagulation defects ..."

Youngest is 7. PCP and Kaposi's sarcoma had been found in this group, five have died.

"It seemed possible that factor VIII or other blood products administered to these patients might be implicated.

"The CDC AIDS Task Force were working on the hypothesis that an infective agent was involved ..."

Then it's said that:

"Further support for this hypothesis had come from the report of three cases associated with whole blood or platelet transfusions. Two were in adults ... The third case was that of a twenty month old boy from California ..."

So the San Francisco baby case there and, if we go on to the next page, we can see reference towards the end of the first paragraph to the papers in the New England Journal of Medicine suggesting that transfusions of concentrate may be a factor. Then

Dr Craske is reporting that:

"The Americans were keen for ... Centre Directors to collaborate in the reporting of cases of AIDS possibly associated with transfusions of ... Factor VIII."

There is then a discussion that the working party (so Dr Rizza, Dr Craske, et al) should undertake some kind of survey, with directors being asked to report patients. Then there is a discussion again of the New England Journal of Medicine papers, and it's said that the main finding was that patients treated with freeze-dried concentrate had lower ratios, that's reference to the T helper suppressor ratios, than patients on cryoprecipitate and normal controls. Dr Craske agrees to draw up a form for the reporting of AIDS cases.

So very clear that as at 19 January, Dr Rizza and indeed the other attendees at the meeting knew about the New England Journal of Medicine, had a discussion about its findings, and the decision that's reached in terms of action by the Hepatitis Working Party is the construction of a form for the reporting of cases. So a degree of surveillance but no other recommendation in relation to any change in approach to the use of factor products.

That's 19 January. We've looked now, sir, on a number of occasions at the minutes of that meeting in the London Airport hotel on 24 January. I won't go back to it now but it was a meeting at which Dr Rizza was present, at which, as we know, the high mortality rate and the long incubation period for the syndrome were both reported.

The next insight we get from the documents in relation to Dr Rizza's knowledge in relation to AIDS is in May of 1983.

If we have OXUH0002245_007, this is a letter from Dr Rizza on 11 May of 1983 to the Regional Medical Officer of the Oxford Regional Health Authority. It's headed "(AIDS)":

"i have just received Dr [Chappell's] 'Case of need' presented to you recently on the above subject and I am writing to say I wholeheartedly support her in her aims to set up a screening programme. There is no doubt that the recent publicity concerning AIDS has created a good deal of apprehension in haemophiliacs, their medical attendants and the DHSS. I think it is important that we act quickly to set up screening tests to detect the patients who might be at risk of developing the full-blown condition."

So, pausing there, sir, again we don't see from

this any decision to change the approach to treatment but there is an expression of the view that it's important to try to assess the possible presentation of any symptoms in patients.

Then he says this:

"... I think it is particularly important to set up tests in Oxford for the following reason. The Oxford Haemophilia Centre is the largest in the country and in addition to using American Factor VIII concentrates are said to carry a risk of transmitting AIDS, we also use large amounts of NHS factor VIII. Our system of treatment is such that many patients have received only NHS factor VIII and others only US concentrates."

Pausing there, it is not currently clear, sir, on the documents at least, why that is the case. Certainly the evidence we heard from individuals who were treated at Oxford suggested a mix of both NHS and commercial concentrates in their individual treatment. We see from that document we looked at earlier the suggestion that young children and adolescents would be treated preferentially with NHS Factor VIII. But it's not clear what that precise system of treatment is or what the basis is for Dr Rizza having treated some patients only with NHS and some with only

US concentrates. He goes on to say:

"It should therefore be possible to find out if patients on NHS concentrates are immuno-suppressed to the same degree as those on US concentrates. The results will have important implications for plasma fractionation policy in this country.

"The matter is one of great urgency and I hope that it will be possible to set up the necessary screening test within the next few weeks."

So we see here what is seen effectively as an opportunity to try to assess relative risks of AIDS from NHS factor concentrates and commercial factor concentrates. No suggestion here that factor concentrates are not the relevant transmissible route of the virus.

SIR BRIAN LANGSTAFF: What do you think might be meant by the last sentence of the penultimate paragraph:

"The results will have important implications for plasma fractionation policy in this country."

Suppose the results show that NHS concentrates produce more immunosuppression than US commercial concentrates, one can see that something might be done about method of production. If it's the other way round, as is his information it is rumoured to be or said to be, what are the implications for policy?

Does it mean that they have to produce more NHS concentrate or cryoprecipitate or what's the possible interpretation of it?

MS RICHARDS: Well, the reference to plasma fractionation policy would tend to suggest it's more likely the former of the two that you suggested, that there would be a more urgent or pressing need for more production of NHS concentrate if that were shown by this proposal for surveillance in screening to be less risky than the US concentrate. It could, I suppose, be talking about policy more generally and a reversion to cryoprecipitate but it's difficult to know. It's a very general statement.

SIR BRIAN LANGSTAFF: Yes. Well, if we do hear from Rizza then we can take it up with him.

MS RICHARDS: We can ask him, yes.

If we go to OXUH0002246_010, we can see that then in early May 1983 Dr Rizza is instrumental in arranging the special meeting of Reference Centre Directors that we know takes place on 13 May.

Although we've looked at it on a number of occasions, sir, if we just look at it, as it were, from the Oxford perspective. The minutes of that meeting are at BPLL0001351_024.

These are the minutes of that special meeting

and we can see it is a small number of directors who attend, including Dr Rizza. So he's the Oxford representative.

We know if we go to the second page that the view that is formed by this small group of Reference Centre Directors in the second paragraph is that there's insufficient information available to warrant changing the type of concentrate used in any particular patient.

Then we know also from the last paragraph, the last few lines, it's also agreed by the meeting that there's insufficient evidence to warrant restriction of the use of imported concentrates in patients other than potentially children and mildly affected haemophiliacs, where we just have the -- or it will be circumspect to continue the policy of using cryo or NHS if that's what you already do.

That, of course, resulted then in the letter that was sent out by Dr Rizza and Professor Bloom on 24 June 1983. We've looked at it on multiple occasions but just to have it briefly on screen for today's purposes, OXUH0000004_005. The June letter. Of course, although these are all materials sent out jointly by Professor Bloom as chair and Dr Rizza as secretary, it is relevant to note that they do

actually come from the Oxford Haemophilia Centre. It is Dr Rizza who is, as it were, at least co-authoring the letter and making the arrangements to send it out.

Henry, if we have HSOC0001272.

We may have looked at this with the Professor Bloom Cardiff presentation. It's Professor Bloom's letter to Dr Boulton on 23 May, but we can see at the bottom this was copied to Dr Rizza, and it may be a fair inference, sir, for you to draw in due course, obviously having heard further evidence no doubt, that the policy and direction of UKHCDO was something in which Dr Rizza himself was closely involved with Professor Bloom.

It's not a very good copy but about six lines down we have Professor Bloom saying, and as I say, probably a fair inference that Dr Rizza agreed:

"I do not think that anyone is complacent about the situation but I think that we all agree that it would be counter-productive to ban the importation of blood products at this moment."

So as at May 1983, clearly the policy of the Reference Centre Directors, including Dr Rizza, is not to change course and not too seek a ban on the import of products.

There is then a letter at OXUH0001612. This is

now 6 July 1983, and it's a letter from Dr Craske to Dr Rizza. The starting point is a paper on non-A, non-B hepatitis after transfusion with Factor VIII, and there's some discussion about that paper in the first paragraph.

Third paragraph, it's clear that there's going to be a discussion between Dr Rizza and Dr Craske at Oxford about the future work in relation to non-A, non-B hepatitis. But then bottom of the page we can see Dr Craske saying that:

"... I and some other PHLS colleagues and Arthur Bloom have been asked to give some evidence to the Committee on the Safety of Medicine on ... July 13th regarding the implications for factor VIII therapy and the possible association of AIDS with factor VIII treatment. If you have any matters which you think I should include in my presentation, perhaps you could let me know next Monday when you return from holiday."

Over the page:

"There are also some political problems regarding cases of AIDS in other countries in Europe. At Arthur's suggestion, I am writing to Professor Lechner in Vienna asking him for details of his case of AIDS in a haemophiliac ... I am going to

try and see whether Kryobulin of American origin could be implicated. I heard a rumour at the Stockholm meeting that they have discontinued the use of this product and are now using a heat-treated German product."

Two observations there, sir. We can see Dr Rizza being expressly invited by Dr Craske to let him know of any particular matters that Dr Rizza thinks should be drawn to the attention of the Committee on Safety of Medicines on the issue of AIDS and Factor VIII concentrates. That's the first observation. The second is Dr Rizza is here being given an update by Dr Craske of developments elsewhere in the world, including the use of a heat-treated German product.

SIR BRIAN LANGSTAFF: Just before we leave this, the second sentence in that last page:

"At Arthur's suggestion, I [that's Craske] am writing to Professor Lechner in Vienna asking him for details of his case of AIDS in a haemophiliac ..."

Does that suggest that -- is the Arthur, do you think, likely to be Arthur Bloom?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Does it suggest that Arthur alerted Craske to the possibility or the probability, what he

had been told, that there was a case of AIDS in a haemophiliac in Vienna?

MS RICHARDS: Yes. Whether it's Professor Bloom alerting Dr Craske or Dr Craske alerting Professor Bloom, it is clear that from this letter that Professor Bloom must have been aware of that case in Vienna.

SIR BRIAN LANGSTAFF: Just going back for a moment to the presentation in respect of Professor Bloom, is there anything in what he was saying to others that demonstrated an awareness of this?

MS RICHARDS: Sir, I'd need to look back at the correspondence he was having in July. He was certainly being asked by The Haemophilia Society in July -- "he" is Professor Bloom -- if he wanted to change or update the advice he had given in early May. I referred yesterday or the previous week to knowledge of German cases.

I think one can say he didn't take the opportunity or he doesn't appear to have taken the opportunity to update his advice to The Haemophilia Society by reference to other European cases such as the Viennese one. What he was saying, either publicly or privately, specifically in July about other European cases I'd need to check, but I think one can certainly make that observation.

On any view, for today's purposes it is all being brought to the attention of Dr Rizza at Oxford.

SIR BRIAN LANGSTAFF: Yes. If it's accurate he would have known of this at least a week before the meeting of 13 July when the committee decided that the risk was insufficient to ban the importation of product.

MS RICHARDS: Yes. Which, as we've seen from the material we've just looked at, represented the collective view of the Reference Centre Directors, Rizza and others.

SIR BRIAN LANGSTAFF: Yes. Well, thank you.

MS RICHARDS: There's then a letter from Dr Rizza on 29 July 1983 which we should look at OXUH0002246_007.

He is writing to a Dr Ebbesen in Denmark. It's declining an invitation to attend an AIDS congress due to be held in Denmark in October of that year. He says this:

"The surveillance of AIDS in UK haemophiliacs is being co-ordinated by Dr J Craske ... It is probably more appropriate for him to attend the meeting.

"With regard to wide surveillance ..."

So not just haemophiliacs.

"... this being undertaken I think by Dr Galbraith ... but I'm not sure what progress has been made in this respect."

Then Dr Rizza says this:

"As far as the haemophiliacs in the UK are concerned, all 110 haemophilia centres have been sent guidelines for diagnosing AIDS, information on tests to be carried out, and samples to be kept. To date there is only one possible AIDS case in a total of 4,500 haemophiliacs in the UK. This patient is being closely observed and all the batches of Factor VIII transfused into him during the past 3 years are being followed up to see which other patients have received those batches and to try to find the donor sources of the batches."

So, sir, two matters which one can potentially draw from this letter. The first is that we are told that all of the haemophilia centres in the UK have been sent guidelines for diagnosing AIDS, information on tests and samples to be kept.

So every haemophilia centre had been provided some information which we will need to look in detail at another stage at what that information might have comprised, but the potential link between AIDS and haemophilia clearly it would seem from this has been drawn to the attention of every haemophilia centre in the country.

The second observation is what's said about the one possible AIDS case, and one notes the emphasis

Dr Rizza has given to this by underlining the word "possible". This is presumably a reference to the Cardiff case and we have information that, indeed information we looked at in the Cardiff presentation, which suggests that certainly by 29 July calling it a possible case may be understating what was known about the case. It's also important to note that it's being said that the patient's being closely observed, presumably under the auspices of Professor Bloom, and all the batches that that patient has received are being followed up.

We've certainly seen some evidence of that in Cardiff records and I referred yesterday morning to one specific case where we had seen a record in April of 1983 about this patient received the same batch as the Cardiff case.

But this shows, it may be fair to infer, close communication between Professor Bloom and Dr Rizza about the steps that are being taken in that regard. Whether the batches are being followed up in other centres and in Oxford we don't know one way or another. But, again, it perhaps assists in understanding how Professor Bloom and Dr Rizza were co-ordinating decision-making and discussing matters throughout this period.

There's an exchange of correspondence, again from this same time, mid-1983, between Dr Rizza and Professor Lee that may be worth looking at. The first in order of time is the letter at OXUH0002971_006. We'll look at the letter in a moment but what we can infer from the correspondence is that around this time Oxford, Dr Rizza was sending samples, presumably from Oxford patients, it's fairly clear from the letter, for testing of T sub-set ratios by the Royal Free. So exploring signs of compromised immunity.

This is Dr Lee writing to Dr Rizza following a telephone conversation and setting out in writing what we're planning to do and she says this:

"I think the main object of looking at T subsets in your patients would be to firmly establish that low ratios are found in patients who are treated with non-commercial concentrate. It would therefore be better to test patient who are severe haemophiliacs with high treatment. It would be nice to look at both haemophilia B and A in order to hopefully confirm our finding that treatment with Factor IX concentrate is not associated with abnormalities in immune regulation."

So going back to earlier correspondence or earlier documents, it appears this is an attempt to

assess relative risks from commercial and non-commercial concentrate:

"Our technician here feels he can cope with about five or six specimens for process on a Tuesday", and then the practical arrangements are set out, and Dr Lee says at the end:

"I look forward to receiving the specimens. I think it would be a very valuable contribution to have these results in a population of patients treated with non-commercial Factor VIII."

So again it would appear that there is a cohort of patients that Dr Rizza has identified who have received only NHS Factor VIII as opposed to other cohorts who have received commercial.

There's a further letter from Dr Lee to Dr Rizza 3 October 1983 at OXUH0002972. Where Dr Lee says to Dr Rizza:

"I'm setting out below our plan for the joint study which we discussed at Oxford and by telephone last week. The aims of the study are (1) to establish the degree of immunological abnormality in a population of heavily treated haemophiliacs treated exclusively with NHS concentrate, and (2) to confirm the differences in T subset distribution we found between patients with haemophilia A and

haemophilia B."

She sets out details of the patients that are required: age, disorder, treatment, weight. She sets out the blood specimens that are required and then, over the page, dates upon which the laboratory has agreed to process the specimens, and then the last paragraph:

"I hope this covers all the details. We look forward to the study becoming a reality. I hope you are not all worn out telephoning patients your end. If we manage to obtain this data it should make a valuable contribution and perhaps even silence the Daily Mail."

We can obviously ask Professor Lee what she meant by that rather than seek to speculate.

Then there's one further letter we can look at to Dr Rizza OXUH0002974_002. Here she is sending preliminary results and says that they are seemingly normal which may turn out to be a reflection of low treatment in this group. Then the last sentence in that paragraph:

"I think our study still has a role to define the degree of abnormality in patients who are virgin as far as commercial concentrate is concerned."

There are various communications in relation to

specific individual test results. If we then go on to OXUH0002977_002 where it's said in the last paragraph:

"It is interesting that the results are still strikingly normal."

Then if we go finally to OXUH0002971_001 this is a letter of 16 November 1983 addressed to Dr Rizza:

"Here are the results for 8 November 1983. Again, they are very normal."

Then we can pick it up the last sentence of the second paragraph:

"I do have a nasty feeling that NHS concentrate is going to turn out safer!"

Again, obviously I can ask Professor Lee what she meant by that comment. For the purposes of considering what was being done at Oxford, we can see that clearly there is a study ongoing as between Oxford and the Royal Free between July and October/November of 1983 in which there is an attempt to assess the relative risks of NHS concentrate as against commercial concentrate and, as I say, on any view hopefully we can shed some further light upon that study when Professor Lee gives evidence.

Just continuing through with the developing position in relation to Dr Rizza's involvement on matters relating to AIDS, we know then in

September 1983 there is a further Reference Centre Directors' meeting. Perhaps we'll look at that, HCDO0000413. Again we can see that Dr Rizza is there present as was Dr Matthews from Oxford.

If we go to the third page please, Henry, under the heading "Current situation regarding AIDS", we can see that the minutes record Dr Craske presenting a paper updating the situation regarding AIDS. There's a discussion about that. There's an agreement that patients who receive the same batches of NHS or commercial Factor VIII as the patient who had died in Bristol should be followed up. So by this time it is known that a patient has died. Donors of the cryoprecipitate received by the Bristol patient are being traced. So the inference from that is the patients received NHS commercial Factor VIII and cryoprecipitate.

There's then concern expressed at the use of commercial concentrates at non-haemophilia centres and there's an agreement that manufacturers of concentrate should be discouraged from selling material to hospitals other than haemophilia centres. It's not quite clear why that is the case. There's then a discussion about plans that the department are considering.

If we go over the page, I think, sir you referred to this yesterday when we were looking at the Galbraith letter or perhaps earlier in the week, there's a discussion about Dr Galbraith's concern that he hadn't heard about the Bristol case until after the patients death, and there's a discussion about reporting cases to Dr Galbraith and the proposal is the reporting of cases will still be through Dr Craske.

Then Dr Craske talks about proposals for an investigation of the epidemiology of AIDS in patients with bleeding disorders. Then over the next page there's reference to Professor Bloom being asked again for an update of the AIDS circular.

So the Reference Centre Directors there, including Dr Rizza, being updated but still no particular action in terms of any change in treatment policy being recommended by those directors.

Again, I'll look later at what Dr Rizza says about some of these events in his litigation report. If we go to -- sorry that's a next document.

We then know that the December 1984 meeting at Elstree was a meeting which Dr Rizza attended and he was presumably part and parcel of the production of the AIDS advisory document dated 14 December 1984.

Again, in his litigation report he talks about the arrangements for the dissemination of that document to other haemophilia centres so I'll come back to that.

There are a number of analyses of data produced by Dr Rizza and Ms Spooner in the second half of the '80s in relation to HTLV-III but, before we look at that, I just want to look next at the developing issue in relation to heat-treated product.

We've seen some of these documents before but I think perhaps when considering Oxford we ought to look back at a couple of them. If we go please, Henry, to CBLA0003258 you will recall, sir, that, as it were, hand-in-hand with the developing knowledge of and response or lack of response to the HIV crisis, Dr Rizza, Professor Bloom and other Reference Centre Directors were occupied with considering proposals in relation to hepatitis-reduced concentrates and we see this document is a letter from Dr Rizza to Dr Lane confirming arrangements for a meeting on 15 December 1982 at BPL to discuss the issue of hepatitis-free or hepatitis-reduced concentrates. We have over the page only here Dr Lane's note of the meeting.

If we look at the second page, please -- sorry, the agenda I should just draw attention to is:

"The implications for the haemophilia and blood transfusion services of the commercial introduction of hepatitis-safe Factor VIII and IX."

So that's the subject of the discussion. If we could then go to the next page, we see there a discussion recorded by Dr Lane of the way in which these potentially hepatitis-reduced products may be used in the United Kingdom either on a named patient basis or for clinical trial, in which case an import licence would be needed and no exemption would be offered. Dr Lane gives his views on how a licence application would be judged.

If we go over the page, we can see that under the heading "Proposals" -- sorry top of the page, you will see Dr Lane's view at least, whether it was a view entirely shared by those at the meeting is unclear but there's a need for centralised fully controlled prospective trials of these materials. Then under the heading "Proposals" Dr Lane is seemingly deploring the potential use by haemophilia directors of these products on a named patient basis.

We then get to the perhaps now infamous letter HCDO0000252_042. So, sir, this is the letter we have looked at on at least one occasion previously that is dated 11 January 1982 but maybe should have been dated

11 January 1983. We looked at it from other perspectives but again important to understand that this is being co-authored by Dr Rizza and sent out under the auspices of the Oxford Haemophilia Centre. We see again in this first paragraph, and I'll just read handful of the relevant lines. Haemophilia Centre Directors are being told by Dr Rizza and Dr Bloom this:

"At least four commercial companies are about to introduce preparations of Factor VIII and possibly Factor IX that have been processed in an attempt to reduce the risk of transmitting hepatitis B and non-A, non-B", and then the process is there described, a form of heat treatment, and reference there to other methods:

"Although batches may have been tested for infectivity by injecting them into chimpanzees it is unlikely that manufacturers will be able to guarantee this form of quality control for all future batches. It is therefore very important to find out by studies in human beings to what extent the infectivity of the various concentrates has been reduced. The most clear-cut way of doing this is by administering those concentrates to patients requiring treatment who have not previously been exposed to large pool

concentrates. Those patients are few in number but [and this is important from the Oxford perspective] a study along these lines is being carried out at Oxford to determine the infectivity of Factor VIII concentrates produced by the PFL and BPL."

Then it goes in to say:

"It is very important to find out and as soon as possible whether the manufacturing methods used to reduce the hepatitis risk has resulted in a product with undesirable characteristics."

Next paragraph:

"Although there's no doubt that the introduction of hepatitis-safe products would constitute a major advance we [so Professor Bloom and Dr Rizza] hope you will agree with us that their use on a named patient basis would be undesirable and might seriously hinder controlled studies in the future. There are several reasons for thinking this", and those reasons are there set out.

Over the page, halfway down the page they say this:

"We are therefore writing to let you know that the Hepatitis Working Party are discussing plans for clinical trials of these products as they become available and will, if necessary, request exemption

from a clinical trial certificate in respect of individual products in order to expedite trials."

So, that's the document set out in January 1983 and of course it is, in fact, the issue of hepatitis-reduced concentrates that was the trigger for the meeting at the Excelsior Hotel Heathrow Airport on 24 January 1983.

We can see then on this issue of trials of heat-treated product correspondence between Dr Rizza and Dr Watt at the Scottish National Blood Transfusion Service a few weeks later.

Henry, if we could have PRSE0000609, please. On 1 March of 1983 Dr Rizza wrote to Dr Watt as follows:

"Dear John, heat treatment of Factor VIII."

He thanks him for a letter.

"I was glad to hear of the progress you are making in the preparation of hepatitis reduced Factor VIII concentrate, especially since three drug companies have been in touch with me in the past three weeks pushing strongly to formalise studies of their different preparations in mildly affected haemophiliacs. I think it will be necessary to use infrequently or previously untransfused haemophiliacs, von Willebrand's patients and carriers of haemophilia to ascertain to what extent hepatitis risk has been

reduced. I see no ethical problem with this. The difficulty with this kind of study has been and always will be I think the small number of previously untransfused patients who come for treatment. At this centre [so at Oxford] we have managed to collect about 30 suitable patients over a two-year period but the patients were not recruited all at once but came in for treatment in the usual random manner, and I think that this should be remembered. In other words, although we may have a group of 500 mildly affected patients on our books only a few of those per year require factor replacement for surgical procedures. I do not think it would be ethically justified to give the material without a good clinical indication. Finally, I certainly would be very keen and willing to try any material that you produce, providing of course that all the other regulatory safeguards have been satisfied."

So further information there, sir, in relation to Oxford both in terms of their own numbers of mildly affected patients but also Dr Rizza's view about how this product could be assessed and in what cohorts of patients, but his view in relation to mildly affected patients, it wouldn't be justified to give this material for the purposes of that assessment without

there being a clinical justification for its use.

There's some further correspondence between Dr Watt and Dr Rizza at HSOC0002719. I'm not sure who's writing the handwriting is. It's 9 March 1983 and its a response to the letter we have just looked at:

"I thank you very much indeed for your letter of 1 March regarding the possibility for study of our new preparation in mildly affected haemophiliacs. I agree completely with the ethical points which you raise and can assure you it is our intention that all regulatory safeguards be fulfilled."

Then he says:

"We'll be carrying out preliminary assessments of clinical efficacy in the near future. I had been concerned that it might prove necessary for us to carry out animals experiments in chimpanzees to satisfy the licensing authority, but have been assured that provided we do not make claims of freedom from infection, this will not be necessary. They would be prepared to accept a claim that the material had been treated in a manner which could be expected to reduce the risk of viral transmission. Apart from the fact that I believe it to be irresponsible to use chimpanzees as laboratory animals for any purpose it

is difficult to understand how two or three controlled administrations can do much beyond encourage hope. The ultimate proof of freedom from the danger of infection transmission will come only when very large numbers of patients have received treatment."

Then there is a further letter between Dr Watt and Dr Rizza but I'm afraid I don't have the reference to that. Picking things up still in March, if we go to HCDO0000003_105, please, we can see then that on 22 March Dr Craske, Dr Rizza and Professor Bloom send out -- this is in the form of a draft letter but they at least propose to send out a letter presumably to Haemophilia Centre Directors headed, "Trials of hepatitis reduced Factor VIII", and it talks about the protocol that's been drawn up by the Hepatitis Working Party for use in trials of the product. The class of patients to be given these products are those who have had no previous treatment with Factor VIII concentrate. The letter recognises it's likely that there are only a limited number of these patients in the UK who will require Factor VIII therapy in any one year and directors are asked to notify Dr Craske of any approaches from commercial firms with a proposal to evaluate the product.

Then it says this:

"It is possible that all products likely to come on to the market within the next year can be catered for if the trials are arranged on a collaborative multi-centre basis. There is a danger that the firm whose product is first on the market will use up all suitable patients if a number of centres evaluate the product without exchanging information. This would mean that a year or so may elapse without adequate trials being arranged for other products. It is also important to ensure that the firm concerned agrees to adhere to the protocol. We hope this will encourage you to identify suitable patients for inclusion in the trial so that these can be located before any products become available."

So there is an invitation there to centre directors to, first of all, to co-ordinate any activities and not simply go off and enrol their patients in trials that the commercial firms may be undertaking and, secondly, to look out for suitable patients who can be enrolled in the trial that the Hepatitis Working Party, which includes Dr Craske and Dr Rizza, wants to undertake.

Before we break for lunch, sir, if we perhaps look at the protocol that's referred to, it's HCDO0000270_044. Sir, we can see here the Hepatitis

Working Party's proposal. Trials of hepatitis reduced Factor VIII concentrate in the NHS, assessment of residual infectivity. The first paragraph refers to the recent development of hepatitis-reduced Factor VIII and it's said it's important to obtain objective evidence as to the safety of these products with regard to a number of matters which include the risk of transfusion of hepatitis.

Then the next paragraph:

"The assessment of residual infectivity of concentrate for non-A, non-B hepatitis and hepatitis B can only be carried out on patients known to be susceptible to non-A, non-B hepatitis."

Reference is made to a study of 30 patients and that was an Oxford study undertaken by, amongst others, Dr Trowell, Dr Rizza and Mrs Fletcher at Oxford.

Patients given Factor VIII "to cover an operative procedure or other treatment" in which:

"... all 9 patients who had not received blood concentrates before, contracted non-B hepatitis after receiving their first transfusion of ... commercial ... or NHS factor VIII."

So that's tells us that there was an Oxford study, sir, the results of which are described in this

document as being in preparation at this time which showed, as it were, 100 per cent attack rate for the nine patients, all developing non-A, non-B hepatitis after first transfusion with concentrate.

Then the protocol continues that the proposal is:

"... to assess the residual infectivity of brands of 'hepatitis reduced' factor VIII by means of a clinical trial ..." in previously untreated patients.

The methods outlined that the decision to include any patient in the trials will be made by the director of the local haemophilia centre responsible for the care of the patient. Then the criteria that are set out include being part of an infrequently treated patient group who's not previously been treated with Factor VIII concentrates. They shouldn't have received any blood products in the six months prior to entry in the trial.

And then --

SIR BRIAN LANGSTAFF: I think we may not be on the same page.

THE WITNESS: It's the paragraph beginning -- it's under the heading "Methods", under the heading "Subjects will be selected".

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Sorry, sir, I'm slightly paraphrasing in the interests of expedition.

So the criteria there for inclusion in the trial, amongst other things, is that you haven't received any blood products in the six months prior to entry in the trial, and preferably that you have received less than 50 donor units of cryoprecipitate in the past and that you have had no previous hepatitis -- that's a few lines further down -- and then the plan for each new product is to prospectively follow the occurrence of hepatitis in a series of ten patients. So it appears that the expectation is that a number of these patients will develop hepatitis.

The procedure is outlined at the bottom of the page. It's said:

"The object of the study will be explaining to them, and their consent of that of their parents obtained, if under 16 years or age."

So it's a study where children are eligible. Precisely what information was intended to be given in order to obtain informed consent we haven't yet fully ascertained, sir.

Over the page, there is description of the detailed clinical examination that will be undertaken.

Then we're told that patients will be followed up for 52 weeks, liver function tests will be undertaken, blood will be tested, et cetera, et cetera. Then we have a definition of hepatitis and how it will be determined if a patient is suffering from acute hepatitis, and it's identified that it could be hepatitis B or non-A, non-B.

There's then reference under the heading "Laboratory Testing" to the hope that the sera obtained from patients will be made available to the Hepatitis Working Party for use when tests for non-A, non-B hepatitis become available. So it appears there, there was a proposal for serum samples from patients that could have been drawn all around the party to be stored in some form of another so the Hepatitis Working Party could access those stored samples in future years.

We're told that a collection of sera from 40 patients with Factor VIII and IX, both NHS and commercial, used in a prospective study at Oxford have been established. So those who have already been in one of the studies being undertaken at Oxford, their sera, it would appear, has been sent to Dr Craske. Again, whether that was known to patients is something which we don't yet currently know.

Then at the bottom of the page:

"Follow-up.

"Patients whose liver function tests remain elevated for one year after the acute attack of non-A, non-B hepatitis or become carriers of hepatitis B virus will be referred to the local liver clinic for investigation of chronic liver disease. Liver biopsy will not be carried out unless clinically indicated."

This is all contemplated as a potential consequence for the patients and then the next page describes how the results will be analysed. Then there are various forms in relation to how the follow-up will be recorded. That's the protocol sent out by Rizza, Craske and Bloom in 1983 to directors inviting them to submit patients for the study.

Sir, I note the time, so that might be the right point at which to stop for now.

SIR BRIAN LANGSTAFF: Yes. Well, I think that would be a convenient moment to break for lunch. Can we be back, please, by 2 o'clock.

(1.01 pm)

(Luncheon Adjournment)

(2.00 pm)

MS RICHARDS: Sir, we have been looking at the protocol for the trials of hepatitis-reduced Factor VIII and

you will recall there was a reference there to an earlier Oxford study. We'll just look at a document which shows prior to the hepatitis-reduced protocol there was earlier research work being undertaken about the incidence of hepatitis more generally at Oxford.

HCDO0000135_015, please.

This is a document dated 23 September 1982, so it's a few months prior to the document we were just looking at. It's entitled:

"A prospective study of the incidence of acute and chronic hepatitis in haemophiliacs as a result of first exposure to Factor VIII and IX concentrate or cryoprecipitate."

We can see it just gives a little further information about research studies at Oxford:

"The hepatitis surveillance programme at Oxford has shown that the group of haemophiliacs with the highest incidence of acute hepatitis are those patients exposed to freeze-dried concentrate for the first time. Most of these are patients with mild coagulation defects who require few transfusions, usually of cryoprecipitate only. Since the risk of chronic hepatitis following an acute attack of non-A, non-B hepatitis after a transfusion of Factor VIII concentrate is between 20 and 40 per cent, it is

important that an accurate estimate should be made of the incidence of transfusion hepatitis in this group."

Then reference to the study involving nine patients:

"A preliminary study carried out at the Oxford Haemophilia Centre showed that 9 out of 9 patients treated with factor VIII or IX concentrate for the first time contracted non-A, non-B hepatitis."

You will see there, sir, that:

"Seven of these patients [received] NHS Factor VIII with a pool size of between 1,426 and 2,504 plasma donations ..."

So larger pool sizes than we had been looking at in the 1970s for NHS concentrate.

Then Dr Craske proposes:

"... to extend these observations by undertaking similar studies in other Haemophilia Centres to compare the incidence of acute hepatitis after first exposure to factor VIII and IX concentrate of different brands and to obtain accurate information about the risk of chronic sequelae. There are also several commercial products under development where attempts have been made to inactivate viruses ..."

So that's the protocol that we see later.

He adds:

"The only way of determining whether any of these methods is effective in inactivating hepatitis viruses in these products is by chimpanzee inoculation or a prospective study in haemophiliacs who have had no previous exposure to concentrate. Chimpanzees are in short supply, so in the absence of laboratory tests for non-A, non-B, hepatitis trials in patients likely to be susceptible to non-A, non-B hepatitis present the only possible way of evaluating this risk."

He gives details of the proposed prospective study.

Whilst we are on the theme of studies involving previously untreated patients, there's a short exchange of correspondence which we should refer to.

Henry, could we have OXUH0000679_002.

This is correspondence between Dr Cash of the Scottish National Blood Transfusion Service and Dr Rizza. This letter is 13 March 1984:

"Dear Charles ...

"As promised, I write to enquire whether you would support the inclusion, in future non-A/non-B hepatitis studies on 'virgin' haemophilia A patients at Oxford, of SNBTS heat-treated Factor VIII."

So the request there to include, in such studies as are being undertaken at Oxford as one of the

products, the SNBTS factor.

And then we see, if we go to OXUH0000679_001. Dr Rizza's reply:

"As I said to you in York last week we here in Oxford would be prepared to include the use of SNBTS heat treated Factor VIII in our studies on non-A non-B hepatitis in previously untransfused patients."

There are further communications in which he shares a protocol and so on.

Then we see at OXUH0000676_001, letter of 10 May 1984 to Dr Cash in relation to the SNBTS heat-treated product:

"I should like to have a look at some of your heat-treated Factor VIII and give it to some of our severely affected haemophiliacs to see what its half-life is and to make sure there are no undue side effects."

So further indication of some of the studies that were being undertaken at Oxford in 1983/1984, or were at least contemplated at Oxford during that time.

In March of 1984, Dr Rizza, Dr Craske and Professor Bloom provided a memorandum updating directors on trials that were being undertaken in relation to the commercial heat-treated products, and we can see that at CBLA0001831.

29 March 1984, the Oxford Haemophilia Centre sends out again information to all UK Haemophilia Centre Directors:

"Trials of 'hepatitis reduced' Factor VIII - an update."

Four lines down, we are told that the authors of this letter, who are Bloom, Craske and Rizza, have:

"... recently reappraised the situation and there are at present 8 different products in preparation or available for trial. Clinical trials have only been completed on one product, the 'Hemofil HT' Factor VIII, which is prepared using a 'dry heat' method. The results indicated that there was still a 63 per cent attack rate of non-A, non-B hepatitis on first exposure to this product in patients who have not received Factor VIII concentrate previously. These trials are difficult to evaluate as for ethical reasons no control group was used."

Then we're told what products are currently available:

"Heated products from Armour, Cutter, Travenol and Alpha ... The 3 former are 'dry heat' preparations and the latter ... is a wet heat ..."

"(2) NHS Factor VIII prepared from a specially selected donor panel ... monitored for abnormal LFTs,

hepatitis, et cetera.

"(3) Heated NHS Factor VIII, one brand is manufactured at the PFC in Edinburgh and will be shortly available."

That's no doubt a reference to the exchange of correspondence we've just looked at.

"The second, manufactured at Elstree, should be available later this year."

Then fourth:

"A heated preparation manufactured by Behringwerke ..."

In Germany, and details are given in relation to that.

At the bottom of the page we can see it being said:

"All products except those derived from NHS Factor VIII are made from plasma imported from the USA, and, therefore, they carry a putative risk of transmission of AIDS."

Then they say:

"It is evident that 8 products will be shortly available on the market and, unless these are co-ordinated, there will not be enough patients available to evaluate each product carefully."

So directors are then invited to draw up a list

of patients in their respective centres who might be suitable for a trial on the basis of previous blood product exposure and who are likely to require treatment with Factor VIII in the near future, and various suggestions are there set out for collaboration between directors in the evaluation of those various heat-treated products.

There was an update provided -- I won't go to it -- in the meeting of the Hepatitis Working Party attended by Dr Rizza later in 1984, September 1984, which reported that the trial of Armour's product had been suspended after an occurrence of hepatitis in two patients and that the Hemofil had shown a 63 incidence of elevated transaminases in patients.

We reach late 1984 and, as already indicated, that key meeting in December 1984 at Elstree, when the decision is made by directors to recommend the use of heat-treated products now on a much wider scale than hitherto.

In terms of what then happened in Oxford as to the availability and use of heat-treated products, we can pick that up in a letter from Dr Rizza to the district treasurer of the Oxfordshire Health Authority.

It's OXUH0003761_020.

It's three days after the meeting at Elstree, 13 December 1984:

"Dear Mr Jones,

"A meeting of the UK Haemophilia Reference Centre Directors was held on 10.12.84 at Elstree to discuss the current problems of AIDS and its impact on blood transfusion practice and haemophilia care."

Refers to who else was there.

"The meeting agreed that all haemophiliacs should receive heat-treated factor concentrates and that all patients should be transferred to this form of treatment, as soon as possible."

Then Dr Rizza says this:

"We should like to pursue this course of action and have already placed our first order for a batch of heated material for use at this Centre."

Then there is reference to the likely cost of that. So it can be seen Dr Rizza expressed here an intention to start using the heat-treated products at this stage.

The response to that letter is at OXUH0003761_019. The district treasurer's response is there's no budget provision to pay for the heat-treated material for use locally, and Dr Rizza was asked to incur further expenditure until the

question of funding had been clarified. That appears to have caused some considerable concern within the health authority, and at OXUH0003761_018 we can see a memo dated 28 December 1984 from someone at the Churchill Hospital to the district treasurer:

"I know Dr Rizza has spoken to you about this but I feel I must reiterate the enormous and wide ranging difficulties your embargo will place on the haemophilia service. The small stock of heat-treated Factor VIII obtained so far will only last about another four to six weeks."

Then he goes on to say:

"If we are unable to obtain heat-treated Factor VIII commercially we run the risk of having to use an inferior material from abroad. As other countries move to heat-treated Factor VIII they will offload supplies of dubious quality onto the UK market. In fact, I understand untreated Factor VIII may be withdrawn from the market in a month or two. We can be more confident about the quality of the NHS supply which will be heat-treated from April 1985 anyway.

"If we cannot continue to use heat-treated supplies we shall also find that staff and patient morale will drop and pressure will mount from the

patients, the general public and the press. To a certain extent we can cope with that if absolutely necessarily but in purely financial terms we could be faced with greater costs through litigation if a preventable untoward incident occurs."

Then the author urges the district treasurer to:

"... bring the greatest possible pressure to bear on your Treasurer colleagues elsewhere so that the Haemophilia Department can buy the most appropriate supplies."

And the letter concludes:

"... I would be grateful if you could see your way to lifting, immediately, the embargo on the purchase of heat-treated Factor VIII."

It's not clear precisely when that embargo was lifted but it does become apparent in the early part of 1985 that heat-treated products were introduced at Oxford. Precisely when, we don't know.

There is, for example, a letter at OXUH0000422_003 from Dr Rizza, it's "Dear [blank]", 30 January, but it's clearly a letter aimed at patients:

"As we discussed when you changed to heated Factor VIII, it is very important that we see you and take a blood sample at monthly intervals, in order to

assess the effect of the new Factor VIII."

Whether by this time this is still the small amount of stock in use or whether Dr Rizza had secured funding to move all patients onto heat-treated product, we don't know, but clearly some patients, at least by the end of January, were receiving a heat-treated product.

SIR BRIAN LANGSTAFF: My recollection from other sources, Inquiry sources, is The Guardian reported, on 20 December 1984, two cases of ordinary transfusion where AIDS was transmitted. One was a 78-year old man and the other was a mother and a baby both being infected. This gave rise to a certain amount of consternation which may, possibly, be linked with a greater willingness to have the additional expense for heat treatment.

I wonder if that can be looked at to see if there's any reflection of that in the documentation.

MS RICHARDS: Certainly, sir. We don't have it available to display at the moment but we can certainly follow that through.

We do know that by June of 1985 Dr Rizza, Dr Bloom and Dr Forbes had written a letter to the British Medical Journal expressing concern that a significant number of haemophilia centres were still

using non heat-treated Factor VIII and Factor IX. It may be that one can infer from that that, at least in Oxford, heat-treated products were now in use across the board.

It's PRSE0001917, please.

Not the easiest document to read. If we zoom in a little closer please, Henry, and go down towards the text of the letter. Thank you.

We can see it's authored by Bloom, Forbes and Rizza:

"We are writing on behalf of the directors of the UK haemophilia reference centres to express our concern about the safety of blood and unheated ... products.

"... (AIDS) is now the most important complication of treatment for haemophilia. By the end of April 1985 over 60 American and 20 European haemophiliacs with this disorder had been reported about half of those had died. In haemophiliacs the prevalence of antibody to the causative agent HTLV-III in the UK has been rising since 1980, mainly due to the use of untreated heated concentrate of factor VIII imported from America. However, seroconversion is also appearing in patients with haemophilia A treated only with Factor VIII concentrates derived from

UK plasma ... and also in patients with haemophilia B treated only with locally produced factor IX concentrate."

Then reference is made to the heat-treated. Then if we could just go back to the whole letter please, Henry, next paragraph says:

"To assess the impact of these recommendations on treatment of haemophilia ... the directors of the 109 haemophilia centres were circulated in May 1985 with a short questionnaire; 83 replies were received ... Many centres were using cryoprecipitate and a substantial number were still using unheated UK Factor VIII concentrate but this may have represented clearing of existing stock. Only a few centres were using heat-treated Factor IX concentrate, presumably because this must be purchased from commercial sources whereas the unheated material is supplied free from the UK manufacturers."

Then they go on to say below:

"The figures have some disturbing implications. Without doubt the prevalence of HTLV-III infection in the homosexual population and other potential blood donors is increasing. The safety of cryoprecipitate and unheated UK blood products with regard to HTLV-III infection can therefore no longer be assumed

especially as these materials may need to be administered in repeated doses."

Then they go on to say:

"We no longer consider the use of cryoprecipitate or other non-heat-treated concentrates is justified."

They make that point both in relation to patients with haemophilia and those who may be at risk from ordinary blood transfusion. Then they go on to talk about the need to introduce screening for blood donations.

That's Dr Rizza's position expressed to the BMJ in June of 1985.

If we go to OXUH0003771_003, please, Henry.

This is a letter from Dr Rizza dated 30 July 1986 to Dr Smithies at the Department of Health.

Sorry, can I have the whole letter. Thank you.

We'll see what Dr Rizza is setting out here in relation to 8Y and the NHS product 8Y. He says:

"As far as I can gather BPL will start releasing 8Y prepared from tested donors by the middle of the August and by the end of September, if not sooner, all the NHS Factor VIII being issued will be from tested donors. There will therefore be a 4-6 week period

during which there will be a gradual change from untested to tested material being issued. I gather that the proportion of untested material issued to begin with may be of the order of 50 per cent."

Then he says:

"I shall be very pleased with all the 8Y produced by BPL is from tested donors but in the meantime I am willing to use, during the 'run-in' period mentioned above, the material prepared from untested donors. The alternative would be to change some of my patients from 8Y factor VIII to one of the commercial preparations. This latter prospect disturbs me greatly and I would be most reluctant to make this change in therapy as I feel that untested but strongly heated 8Y is probably safer than the anti-HIV tested but less strongly heated commercial material from the point of view of transmitting HIV infection and hepatitis."

Then we see he sets out the position as at June 1985 onwards:

"We have been using 8Y material from untested donors at this Centre from June 1985 until the present time. More than thirty patients are receiving it routinely. To date no patient has sero-converted to being HIV positive. Furthermore, there has to date

been no evidence of transmission of Non A Non B hepatitis using this material in patients not previously transfused or only infrequently transfused."

He goes on to set out his view that heated commercial preparations still transmit non-A, non-B hepatitis. Then this:

"The decision to use or not to use the untested 8Y, if it is released, will ultimately depend on each director's clinical judgment. For the reasons given above, I personally am prepared to use it rather than change some of my patients from NHS material to a commercial product."

So we can see there, sir, in terms of product usage at Oxford, 8Y had been in use from June 1985 onwards, presumably commercial heat-treated product had been used in the first half of 1985 and then, in the middle of 1986, there is this question or dilemma as to whether to continue using that pending the introduction of 8Y prepared from tested donors. We can see there Dr Rizza's position set out.

During this period, from 1985 to 1988, Oxford was collecting data on HTLV-III testing from other haemophilia centres and analysing that data.

If we go please, Henry, to PRSE0000476.

This is a document authored by Dr Rizza and Ms Spooner at Oxford, dated 27 September 1985. It's an "Interim report on survey of HTLV-III antibody in haemophiliacs in UK", and says this:

"Following the request for information on HTLV-III antibody status of patients attending the 109 haemophilia centres in the UK, we received reports from 81 (74 per cent) centres. Four centres said that they could not co-operate because of the problem of confidentiality but 3 said they would try to provide information later."

And then the results. I won't go through the detail of all the results but we can see Dr Rizza recording that by this time, September 1985, a total of 2,570 patients have been tested. The results change over the years as more are rested.

If we go on to PRSE0003912, this is a report the following year from Dr Rizza and Ms Spooner at Oxford. It's dated 3 October 1986, and it's effectively a follow-up:

"Provisional Report on 1986 survey of anti-HIV in haemophiliacs in UK.

"Each of the 109 Haemophilia Centres in the UK were sent a printout in May 1986 ..."

Sent, I think inferentially, by Oxford:

"... showing the names of patients who had been treated at that Centre in the period 1980-85. The Director was asked to denote on the printout those patients who had been tested for anti-HIV, the most recent test result and the date of the test. Directors were asked to return the information by 9 July. The procedure was the same as that used in the 1985 survey ..."

Which we just looked at.

Then the results:

"To date reports have been received from 84 centres. As in the 1985 survey ... several centres have not sent information because of their concern about confidentiality. Thirteen centres which contributed data in 1985 did not do so in 1986 and 14 which had not contributed in 1985 did so in 1986."

So the point is made that there can't be a precise comparison between the results.

But you will see there, sir, the procedure that was being undertaken. Oxford sent out the names of patients it had on its register and directors were asked to submit named patient details of HIV results to Oxford. We see a small number of centres declining to do so on confidentiality grounds.

Whether patients were ever told, either by

Oxford or by their own centres, that information about their HIV status was being submitted, with their names, to Oxford is obviously a matter you may wish to consider further.

Then this process is repeated in 1987, OXUH0001219_007. This is:

"Report on 1987 survey of anti-HIV in haemophiliacs in the UK."

We're told again it's authored by Dr Rizza and Ms Spooner. The date of this is 29 January 1988:

"As in the previous 2 surveys each of the 109 Haemophilia Centres in the UK was sent a printout in 1987 showing the names of patients who had been treated at that Centre in the period 1980-86. The Director was asked to denote on the printout those patients who had been tested for anti-HIV, the most recent test result and the date of the test. In addition ..."

So this is the new information in the 1987 survey:

"... the directors were invited to provide information on the sexual partners of their haemophiliac patients. We asked:

"1. If the sexual partners had been tested for anti-HIV.

"2. What result had been obtained.

"3. The date of the last test.

"4. If the test was positive what was the date of the first positive test and the date of the last negative test."

Now it's then said that:

"If the Directors wished the information could be sent to Oxford in an anonymous form by omitting the names of the patients and leaving behind the Diagnosis/Registration number."

Pausing there, it seemed to be the case nonetheless, though, that although the document sent by the directors might not include a name, the analysis by Oxford would enable them to match names to patients because they have those relevant registration numbers.

It said:

"All information was handled in Oxford in strict confidence and no named patient data was entered into the computer."

The results:

"To date reports have been received from 100 Centres. As in the 1985 and 86 surveys ... several centres have not sent information because of their concern about confidentiality."

If we go over the page we can see the results reported in relation to sexual partners. So this information was sent by individual centres to Oxford:

"Information about anti-HIV status was obtained from female sexual partners of 333 haemophiliacs who were antibody positive."

Pausing there again, sir, whether the partners were informed that this information was being transmitted to Oxford is no doubt a matter you will wish to consider.

"Three hundred and thirty nine women were tested and of these 18 (5.3 per cent) were found to be positive. Reports were also received from 78 partners of 78 haemophiliacs who were antibody negative; all of these women were negative. In the case of Christmas disease 7 partners of 6 antibody positive men were tested and 1 was found to be positive. Fifteen partners of 15 antibody negative men were all found to be negative."

Someone has handwritten on this at the bottom:

"To date 81 AIDS, 53 deaths."

Then if we go, Henry, please, to OXUH0002251_014, we can see this is a draft, dated 21 October 1988, of what appears to be a report for publication. It's authored by a number of individuals

at Imperial, the Imperial Cancer Research Fund Cancer Epidemiology and Clinical Trials Unit, University of Oxford, and at the Oxford Haemophilia Centre, and its authors include Dr Rizza and Ms Spooner.

The title is "Seropositivity for HIV and incidence of AIDS and AIDS related complex in UK haemophiliacs: report on behalf of the directors of haemophilia centres in the UK".

If we go to the second page, we can see some figures:

"Out of the 3,545 haemophiliacs in the UK who had received blood products in the period 1980-87 and who had been tested for HIV antibody, 1,179 patients with haemophilia A and 27 patients with haemophilia B were seropositive. No seroconversions are known to have taken place after November 1986."

Then there is discussion about the rate of progression to AIDS.

Turning then, sir, to arrangements within Oxford Regional Health Authority on matters relating to patients infected with HIV, could we have OXUH0002260_076 please, Henry.

We'll see this is the Oxford Regional Health Authority minutes of a meeting of the AIDS clinical working group held on 27 January 1988, and the list of

attendees includes Dr Rizza. It's a broader working group looking at the position of patients infected with AIDS across the Oxfordshire area including but not limited to those infected through blood products.

If we turn to page 3, we can see under the heading "Testing for HIV/AIDS" there is a discussion at this January 1988 meeting about the issue of consent, and there's reference to a draft Oxford BTS, Blood Transfusion Service, screening policy for antibody to HIV. It's said that the paper:

"... had been considered ... by the AIDS Policy Advisory Group who had expressed sympathy with the dilemma posed for the BTS but had felt strongly that no sample should be tested for HIV without confirmation that informed consent had been obtained."

So the issue here was about testing of samples presumably of donors but it's a discussion within Oxford of informed consent and therefore useful to look at for you, sir, more broadly.

"Testing without such consent would be contrary to national and the developing regional policy and legal advice."

We can see in the next paragraph what it said, that the samples in question are non-blood donor samples.

Over the page, the second paragraph is:

"Members could not support the concept of testing non-donor samples without confirmation that informed consent had been obtained."

Sir, you may wish to note the timing of this. It is January 1988. We looked at, with Dr Colvin, the GMC publication in the course of 1988. It would appear that, without needing that, in Oxfordshire the issue of informed consent has at least by January 1988 been addressed or is being addressed and considered.

There is also then on this page reference to an award by the Wellcome Trust of a grant for a five-year study of the psychological state of HIV positive haemophilia patients, and Dr Catalan is recorded as reporting that the study will be of:

"... the psychological state, a range of related issues and neuropsychiatric state of all HIV positive patients in the Oxford Haemophilia Centre compared with a sample of negative haemophiliacs."

Then further information is set out below about the intended psychiatric and neuropsychological testing of HIV-infected individuals.

So that is a further study carried out in Oxford.

In 1989, the following year, there were two

inquests held for HIV positive patients at the Oxford Haemophilia Centre who died in the Oxford area.

In the first, HIV was, as a matter of fact, held by the coroner not to be a contributory factor, but in the second there was some communication between the coroner and Dr Rizza.

If we have OXUH0001262_007.

This is a letter dated 17 April 1989 from the Oxford coroner to Dr Rizza, and it considers the issue of the death certificates and coronial investigation. It's apparent from the opening of the letter that there has been a telephone discussion between Dr Rizza and the coroner and then the coroner says this:

"... I did write to the Secretary of the Coroner's Society and he confirms my own view that there is no easy answer to the problem. I understand that the Registrar General has issued general instructions to registrars of death that if the infection appears on the doctor's certificate they should not enquire how it was caught. For this amongst other reasons only a very small number of cases are likely to be reported to me at all and cases that are reported to me will normally be where the HIV status of the deceased has nothing to do with the cause of death, eg a road accident or even

a suicide ...

"The above does not however help in cases such as the cases of ..."

The individuals there.

Reference is made to the 1988 Coroner's Act, and then the coroner says this, in terms of the obligation to investigate a potential unnatural death:

"'Unnatural' is not capable of exact definition but certainly if a person is infected eg as a result of voluntary sexual activities I would not regard it as unnatural. However, it is difficult to regard a transfusion as a natural process and if, as in these cases, I'm told that a person was infected with HIV as a result of a transfusion with a contaminated product and dies as a result of the infection, I think I am bound to fulfil my statutory function."

Then he goes on to say:

"I am, of course, very well aware of the distress that these cases can cause relatives, particularly if publicity results, and will always do my best to minimise such consequences."

If we go over the page, the coroner says as follows:

"... it is my understanding that Mr [X] as a haemophilia victim was under the care of your unit

and that at some time in the past contracted the HIV infection from blood products given to him. If this is the case then a statement from you on the lines of the one you gave in [another case] is probably all that is required and unless you actually wish to attend could probably be accepted in documentary form. If in your statement you are able confirm with reasonable certainty the source of the infection and assuming I have no other information to the contrary I would not feel bound to enquire into other possible sources of infection ..."

Then he says:

"I do not wish to put words into your mouth but if it is the case I would certainly have no objection to your saying that although contamination was a problem in the past, advances in knowledge and testing procedures have eliminated it."

So, sir, you will see there the coroner's view in Oxford that where there had been a death from HIV where the individual was a patient with a bleeding disorder that was how the person had been infected there would need to be a coronial investigation, albeit that the extent of the investigation appears to have been relatively limited.

You'll see the invitation that the coroner

issued to Dr Rizza to say the problem's now eliminated. Dr Rizza's report in the second case, I won't put it up on screen because although names have been redacted it is possible that someone will be able to work out who it is referring to and may not be aware of the material being used publicly today.

So Dr Rizza did provide a report about the care of the individual who had died and in respect of whom the coroner was holding an inquest, and it was someone who Dr Rizza reported was tested in early 1985 and found to be anti-HIV positive. Tests were carried out on stored serum samples and showed that the patient had been anti-HIV positive since 23 August 1984. Whether that was the date of seroconversion is not however clear because there were earlier stored samples that were tested as well.

Dr Rizza did not take up the invitation to say that there is no future prospect of contamination in that report.

Around this time, the late 1980s, of course, the test for non-A, non-B hepatitis, now known as hepatitis C, was being developed and if we please have OXUH0000725_005 we can see that Dr Smith of PFL wrote to Dr Rizza on 24 July 1989 explaining that there was now a candidate test for hepatitis C developed by

Chiron and marketed by Ortho. He asks if Dr Rizza had already supplied samples for this test to Dr Mortimer at PHLS and if so, to know the result and a summary of the products used by the patient, "since entering our study", so again there is reference there to an ongoing study. Then he says:

"If you have not yet forwarded samples to PHLS I would be pleased to make arrangements for the testing of any remaining samples or a current sample from the patient if he has used only our concentrate."

Over the page Dr Smith asks for Dr Rizza to also confirm the most recent anti-HIV test on the patient, note whether any clinical or lab evidence since completion of the non-A, non-B hepatitis trial might suggest transmission of a blood-borne virus and says:

"I hope you will agree that these extra tests will help to make the fullest use of a unique group of patients in a difficult sampling programme."

We know that HCV testing was then undertaken. The precise date range for the tests in Oxford are not entirely clear but if we look at OXUH0001861_002, we can see that Dr Rizza on 17 July 1991 wrote to Dr Cash, now Professor Cash, with results of the HCV testing that had been undertaken in Oxford:

"I've just looked through the results of our HCV

testing in our patients with haemophilia A, haemophilia B and von Willebrand's disease and without analysing the figures in any great detail it looks as if 63 per cent of 379 patients with haemophilia A, 57 per cent of 61 patients with haemophilia B and 20 per cent of 39 patients with von Willebrand's disease are anti-HCV positive. I should stress that those are Oxford Haemophilia Centre data not UK data."

So those are the figures provided as at July of 1991. A little before that we have a summary of figures for HIV test results in Oxford. That is at OXUH0001299_005. This is a letter dated 9 June 1989 from Dr Rizza to a medical officer within the AIDS unit of the Department of Health and Social Security and he says this:

"The situation at the Oxford Haemophilia Centre is as follows [so this is in relation to HIV] we have at present 135 HIV antibody positive haemophiliacs, a total of 14 of those have developed AIDS, of whom 7 have died. Of the remaining 7 AIDS cases 6 are receiving treatment with AZT and have been receiving the drug for 15, 8, 7, 6, 6 and 4 months. One of the 7 patients who died received AZT for three months before death. Of the patients taking AZT three have had to stop treatment temporarily because of anaemia

requiring blood transfusion or because of severe nausea. At this centre we have used AZT only in patients diagnosed as suffering from AIDS. We have not used AZT in other patients but are participating in the MRC Concord 1 study. To date only 3 of the 60 patients approached have agreed to enter this study."

So there is the -- there are the figures of the numbers of those infected with HIV at Oxford under the care of Dr Rizza as at June 1989, sir.

If we go to OXUH0001863_002, we will see here a letter from Professor Tedder to Dr Rizza June 1991. This was looking at the issue of HCV infections in spouses of haemophiliacs and you'll see the issue raised by Professor Tedder:

"I am faced with increasing problems over counselling patients found to be infected with HCV who wish to know of the risk of transmitting this to their spouses."

He goes on to say:

"It concerns me that we do not know what the transmission rate is."

Dr Rizza's response is at OXUH0001863_001, second page please, Henry, 25 June 1991, from Dr Rizza to Professor Tedder. He says this:

"I am very anxious to find out to what extent

there has been sexual transmission of HCV to the spouses of HCV positive haemophiliacs. As you know, one of the early serological methods revealed a rate of transmission approaching 20 per cent in our group. Given the uncertainties of method, I have found it extreme difficult to know what to say to the couples. They are aware of the tests that are becoming available and may wish to know what a positive result means. I am very keen, therefore, to pursue the problem as quickly as possible and welcome your offer of help."

You will see there, sir, the issue in mid-991 as to what to know and therefore what to say to patients about the risk of sexual transmission. We see the same concern being expressed by Dr Rizza in the following month OXUH0001864. Go to the second page. This is a letter from Dr Rizza dated 11 July '91 to a virologist at John Radcliffe Hospital:

"Here as promised are some of my thoughts on HCV testing in our patients. As I mentioned when you came to visit me the other day, many of our patients and their partners are aware that HCV testing is now available. They are asking about it and several questions have been raised as a consequence, in particular what does it mean if a person is anti-HCV

positive? Is their antibody protective? Are patients that are anti-HCV positive more likely to go on and develop chronic liver disease? Finally, and the most important, are anti-HCV positive patients infectious and likely to transmit it to their sexual partners? To date I have told our patients that the test methods for anti-HCV are being evaluated and that I was not prepared to give a definite answer on the results."

Sir, you can see there uncertainty being expressed by Dr Rizza as to what to tell patients. It's not entirely easy to reconcile this letter which suggests that patients know that HCV testing is available but don't seem to think that they have necessarily been tested -- it's not clear -- with the letter that we looked at a few moments ago that Dr Rizza wrote to Dr Cash six days after this saying these are our results. So there is perhaps a tension there as to whether the test results had been communicated to patients by this time and, if so, what had been said to the patients about their significance and of course you, sir, will know from the written and oral evidence you have heard that delays in being given test results for HCV are a theme of the evidence. They are a theme that emerge in relation to evidence the Inquiry has received from Oxford patients

as well as from patients in other centres across the country.

If we go to OXUH0001862_002, please, Henry, we can see that around this time a meeting is proposed. This is being sent out by the virology department in Oxford and the agenda is BTS testing for HCV from 1 September 1991, so that's Transfusion Service, but then HCV tests on significance and management of positive results. Those attending include Dr Rizza and Dr Trowell.

Then we don't have minutes but we've got a document at OXUH0001862_003. We have a document which is dated July 1991, produced by the Oxford Regional Blood Transfusion Centre. This is:

"Recommendations and information for donors/patients found HCV antibody positive. Donors confirmed as being HCV antibody positive should be referred to their GP."

So that's specifically dealing with the position of donors and then various matters are set out as to what information should then be given to the patient/donor. Breaking the news, it's said:

"The initial news breaking has been done by a letter to the donor from" --

SIR BRIAN LANGSTAFF: That's, I think, not on the

screen -- oh, it is now.

MS RICHARDS: Thank you, sir. At the RTC, so this is the information that the blood donors will be given. What we don't know is the extent to which -- how it was proposed to be delivered to patients at the haemophilia centre.

We see at the bottom what the patient should be told, that chronic liver damage can occur, hence the liver function should be tested:

"If abnormalities are found long-term follow-up will be needed. Even where abnormal liver function is found the outcome is good in most cases and treatment is available when more severe liver disease occurs."

Then:

"Little is known how the virus spreads in the population but sexual transmission does not readily occur."

Then there's more detailed suggested answers that doctors may wish to give. This is intended for GPs to whom donors whose sample has been tested and have been told of the result will be referred.

We haven't found any equivalent document prepared by the Haemophilia Centre or anywhere else within Oxford that sets out how haemophilia patients might have been told of their result and the kind of

information that would be given to them, so whilst there's a model set of information for blood donors, there doesn't appear to be a model set of information for haemophilia patients.

Then if we go to OXUH0001860_002 we can see from this letter, which is from the virology lab at the John Radcliffe Hospital in Oxford to Dr Rizza, 23 August 1990, that's almost certainly a mistake, in 1991, I can explain why in a moment if need be. This is a letter which shows that the virology lab has been doing hepatitis C testing on the wives of haemophilia patients:

"We have tested the following of your list and noted their results. You will see that they are at considerable variation with previous ones. The previous ones are very unreliable, as I have made clear to you on previous occasions. We did not test all the sera you noted as not all are available. Also, one wife has been added."

Then we can see from the results that there's one result identified as positive on this page. The remainder are negative.

If we go to the next page there's a further positive result and it says seroconverted October 1990 or thereabouts. That's one of the reasons why this

seems to be a misdated letter.

"I trust you find these results interesting. We will proceed to test with PCR the patients."

SIR BRIAN LANGSTAFF: The positives, I think.

MS RICHARDS: The positives, sorry and then there is a follow-up letter at OXUH0001860_001. Next page, so this is a letter from Dr Rizza to the virology lab dated 3 September '91. It thanks him for the letter of 23 August 1991 so it seems fairly clear that the previous letter had been misdated:

"Thank you for your letter of 23 August 1991 with the enclosed results of the anti-HCV on some of the wives of our haemophiliacs. I found the results most interesting, especially the results of our patient [Mrs X] samples. As you may remember she recently was found to be anti-HIV positive. I think as you suggested it would be useful to do some of those previously found negative just in case some of them are in fact positive. I have asked Mary Fletcher [that's the clinical nurse specialist] to look through our data to see what information we have on liver function tests on these women."

So that's the position in relation to HCV testing as at 1991 in Oxford. Can I then just draw your attention, sir, to a document about records if

I can find the right reference. This is moving on to a separate topic about medical records, OXUH0001158 I think. Next page. Yes.

So, sir, this is moving to a completely different topic now. This is the question of medical records and this is just a letter that you may find instructive. It's dated 30 May 1975:

"I was very perturbed to learn today that the file for one of our Christmas disease patients had been microfilmed then destroyed without prior reference to me. Haemophiliac and Christmas disease patients can return to Oxford for advice or treatment after long absences, even after 20 years, and even if the original patient does not himself return to Oxford his grandsons or other relatives may be referred to us and the original file required. I, therefore, do not think it is a good policy to destroy these files, even if they have first been microfilmed. Could you please ensure that no further files on haemophilic or Christmas disease patients are destroyed without my approval. If you find that you can no longer keep old files in your department we would prefer to store them ourselves at the centre rather than have them destroyed."

Sir, you will know from the evidence you've

heard again from Oxford, as well as from other centres across the country, that in relation to many of the individuals who provided statements to the Inquiry their records are either incomplete or have been destroyed, at least in part, and that has certainly been a complaint by some individuals who gave evidence about their treatment at the Oxford Haemophilia Centre.

Sir, before I talk a little about research and then move to consider Dr Rizza's litigation report, there are just a couple of documents that are relevant to the issue of stigma. First of all, OXUH0001293_006. This is a letter dated 13 September 1990 from the Nuffield Orthopaedic Centre of the Oxfordshire Health Authority. It's copied to Dr Rizza at the Haemophilia Centre:

"This morning I've had a visit from Mr Inman and Mr Juniper which stems from a letter received by the Dental Department ... I have not seen a copy of this letter. I am sure that one will be forthcoming soon, however it is Dr Johnson's opinion that work in the Dental Department on patients with HIV/hepatitis B cannot be justified in the future on grounds of safety. This all has to do with the AIDS money which was made available from region to district which has

only been partially invested in the current year by the district in HIV-related problems."

Then there's a reference to a bid for money being turned down:

"I have had no alternative other than to agree with the dental department and Dr Johnson and they have been informed that work on patients affected by HIV or hepatitis B will be discontinued as from 1 October. This is a matter of strategic importance to this hospital as we have always provided a comprehensive service, particularly for the haemophiliacs."

Then there's discussion of what other arrangements will have to be made. So you will see there, sir, a lack of willingness to continue to provide dental treatment to patients with HIV or hepatitis B.

Then if we turn to OXUH0001374, this is a letter written -- sorry, next page, 21 March 1991, from a Dr O'Callaghan who is recorded as being an SHO to Dr Rizza, so it is written on behalf of the Oxford Haemophilia Centre to the Buckinghamshire Ambulance Service and it would appear that the haemophilia centre is having to provide some assurance to the Ambulance Service that it is safe to transport

patients with HIV. It says this:

"Further to our telephone conversation of 18 March 1991, I write regarding your concern for the transport of haemophiliac patients, a proportion of whom will be HIV positive as a result of blood product transfusion. There is no evidence that normal social contact with persons infected with the HIV virus poses any risk of infection. Contact with body fluids may pose a risk of infection and precaution should be taken when dealing with patients who are bleeding as a result of external injury or who are vomiting, et cetera. Most of our patients being transported, however, have problems such as bleeding to joints and this, therefore, does not pose a risk as there will be no contact with body fluids. Therefore, while the possibility of HIV infection should be borne in mind, I would stress that these patients should be treated in much the same way as everyone else and can be safely transported in hospital cars."

So it's clear there that a local issue had arisen with the Ambulance Service being concerned about transporting in ordinary Ambulance Service transport haemophiliac patients because of the fear of transmission of HIV.

Sir, I just want to deal, if I may briefly, with

issues relating to research and then perhaps take the break after that. We know that Oxford was a hub for haemophilia research, as we've seen some of the research products that were undertaken over the years. As I indicated at the outset this morning, there is a lot more work still to be undertaken in analysing what research was done, where there was ethical committee approval or not, what the issues were or what the evidence is in relation to patient consent and information and so on. I'm not going to go into detail today about research because the picture presented would inevitably be a very incomplete one.

One aspect of Oxford's work, however, that has come up that you will have seen is the analysis of annual runs data and that was a hugely important part of the work undertaken by the Oxford Haemophilia Centre. It received and analysed data returns from other haemophilia centres on an annual basis from the late 1960s onwards and the information on those returns was then used by Oxford itself, the UKHCDO and its working parties to study a variety of issues.

In terms of the process, there's a document from Dr Rizza which describes it. It's at OXUH0001534_002. This is dated 13 April 1982. If we go to the second page, this is the letter from Dr Rizza, 13 April 1982.

In the final main paragraph we can see a description of the work done at Oxford for UK Haemophilia Centre Directors. It said:

"It includes the patient's name, date of birth, centre at which he is registered, whether or not he has antibodies to Factor VIII, whether or not he is on home treatment and also amount of Factor VIII or IX used. All this kind of information is collected once a year from the centres around the UK and analysed and then included in an annual report sent out to the centres."

So there's a brief overview of the annual return's work. We have looked at some of the annual returns of Dr Winter and Dr Colvin and the general part of the annual returns which set out which products were used in what quantities for hospital and home treatment in the course of a given calendar year but, as this letter from Dr Rizza makes clear, there was also information provided on an annual basis about individual patient treatments and that's confirmed in this letter.

Just one further document on this issue. At HCDO0000248_010, this is a document authored by Dr Rizza on 22 September 1986. It's headed "Concerning Confidentiality of UK Haemophilia Centre

Directors Data Sent to Oxford for Storage and Analysis" and it explains that:

"The directors have been collecting information on haemophilia and its management since 1967. The collection of this information has been co-ordinated and analysed by the Oxford centre. Until 1977, those data were handled manually. Since 1977, some of the information sent to Oxford has been handled using a system on the ICL 2900 at the Oxford Regional Computer Unit. This memorandum discusses the type of information sent to Oxford and the way in which its handled there."

Then we can see he describes how at the beginning of each year all directors are sent a package of forms requesting information on patients for the various bleeding disorders:

"Forms A1 to A7 deal with the total amount of the different therapeutic materials used to treat the different categories of patients during the previous year. Those seven forms do not contain the names of patients. Form A8 collects information on patients who have died in a particular year and asks for the name of patient, diagnosis, date of the birth, date of death, cause of death. Forms B1, B2 and B3 are used throughout for notification of new cases and in

various categories. Those forms ask for the name of the centre, the patient's name in full, sex, date of birth, home town, et cetera, et cetera. Form C1 and C2 are concerned with the survey of hepatitis and request the patient's name, date of the birth, clinical and laboratory details of the patients' hepatitis, possible contact with other cases of hepatitis sought" et cetera, and so you will see there's quite detailed information in those forms.

There's then a form for notification of von Willebrand's disease; a form to notify amendments required to update information about patients; change of name; change of diagnosis; date of death.

Then there's an AIDS form used for surveillance of AIDS-related illness. This form asks for the patient's name or code number, date of the birth and national file number:

"Detailed questions are asked about the patient's anti-HIV status, clinical symptoms, laboratory result" --

SIR BRIAN LANGSTAFF: Just pausing there for a moment, you didn't read out, but it might be important:

"Form AIDS/3 is marked confidential."

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Is that the only form in respect of

which this document says the words confidential is to be the marking?

MS RICHARDS: Yes, I think so. We've seen other forms in which certainly patient names are given and there's no suggestion it's marked confidential, because I think it's particular stigma associated with AIDS which has led to that form being marked as confidential.

SIR BRIAN LANGSTAFF: So all the other information is not marked confidential?

MS RICHARDS: That is an inference that you may wish to draw from this.

SIR BRIAN LANGSTAFF: Well, it's a fact. It's not marked "confidential". Whether it was confidential is a question of inference, I think.

MS RICHARDS: Then we can see it records information about sexual preferences, parenteral drug abuse and possible contact with suspected AIDS patients is enquired about. Information on household contacts of the patient is also sought. Then reference to the surveys that I showed you earlier and then, towards the bottom of the page:

"Other forms are sent to directors when necessary to request information."

Pausing there, whether patients were aware that data of this kind was being sent to Oxford by their

Haemophilia Centre Directors is clearly a matter that you will wish to consider further.

If we go to the next page, we see under the heading:

"Handling of Data at Oxford. All of the raw information sent to the centre is handled at the centre by Ms Spooner. Some of the information is handled by Mrs Patricia Wallace, a long-standing member of staff and former personal secretary to Dr Rizza. The work is carried out in an office dedicated to the statistical work. The office can be locked and contains lockable cupboards which are used for particularly sensitive data.

"Keying-in of the data into the computer is carried out at the computer centre where the computer centre key-to-disc staff from data transmission sheets filled in by Ms Spooner and Mrs Wallace. Patient data are not sent by telephone from the centre to the computer centre. It should be noted that information in form AIDS/3 is not put into the computer but is kept in a locked cupboard in the dedicated room mentioned above. In Oxford, form AIDS/3 is seen only by Dr Rizza and Ms Spooner. The information is sent in confidence to Dr John Craske in Manchester for analysis. In Manchester, the information is kept in

a locked cupboard and is not placed on a computer."

Then there is further information over the page about how the information can be disseminated in the form of statistical reports. At the top of the page it tells is that:

"... the information on named patients held n the computer can be retrieved only by Ms Spooner."

It's said:

"It will require a lot of expertise and time to break the codes and passwords."

Then a few lines further down:

"Information on a named patient is sent only to the director looking after the patient."

Then there's information about returns and consideration of the Data Protection Act.

Sir, we've heard reference to a later debate in the 1990s about requirements for patient consent for inclusion of data on the National Haemophilia Database. It would appear from this that the issue was being flagged up back in the mid-1980s because one assumes that this report has been produced by Dr Rizza for a reason and, inferentially, it may be the reason is someone has expressed some concern about the issue.

Sir, is that a convenient moment at which to break?

SIR BRIAN LANGSTAFF: Yes, it is. Shall we meet back at 3.45.

(3.14 pm)

(A short break)

(3.45 pm)

MS RICHARDS: Sir, just on the question of research and sharing of information, could we have JEVA0000006, please, Henry. *(Pause)*

I can explain what it is, in any event. It's a study carried out by Bloomberg in the States. It's called a "Study of the occurrence of various inherited and acquired antigens and antibodies in the blood of patients with haemophilia who have been seen at the Oxford Haemophilia Centre". It's a 1972 study and what it appears to show is that data about patients at the Oxford Haemophilia Centre were shared with the author of the study, Bloomberg, for the purposes of the analysis that he was undertaking.

One of the interesting facts about this information is that there appear to have been punch cards for each patient of the Oxford Haemophilia Centre, and the punch cards held a range of data about the patient, and this documentation that's been shared with the Inquiry by a Core Participant seems to suggest that the punch cards themselves, or the

information from punch cards, may have been provided for the purposes of the study. Again, it raises an issue the patient consent about information sharing.

Don't worry about looking for it, Henry.

In terms of other research and trials I have referred to a number of those in the course of the presentation today and the Inquiry will come back to that at an appropriate stage in its work.

I've mentioned obviously Dr Rizza's role as a central figure in UKHCDO and listed a number of the committees or working parties that he was part of. One that I haven't mentioned so far should be found at CABO0000195_036.

Do you have that, Henry?

If we go to the next page -- it's just an extract which I want. If you go to page 63, please, Henry. Thank you.

We can see from this, it's headed "Committee structure and membership". MRC is presumably the Medical Research Council. We can see there's and AIDS Committee and then a number of offshoots, including an Epidemiological Studies Committee.

If we go to page 64, Henry, we can see, almost halfway down the page, the heading "Epidemiological Studies Committee". Zoom in on that. We can see the

members include a number of familiar names: Dr Galbraith, Dr Gunson and Dr Rizza, of the Oxford Haemophilia Centre.

Then if we just go further down that page to its terms of reference, we can see the terms of reference of this particular committee or subcommittee was:

"To review information and research on the natural history and transmission of AIDS in the UK and abroad, and, in particular, the evidence concerning heterosexual transmission. This should include the female partners of bisexual men ..."

Then this:

"... the spouses of haemophiliacs who are HTLV-III positive and the spouses, male and female, of persons infected through blood transfusion."

Then:

"To co-ordinate research within the UK in this area."

So this is another committee upon which Dr Rizza served. This is in the second of the 1980s.

We also understand that Dr Rizza had a long-standing relationship with The Haemophilia Society. He was at one stage a member of The Haemophilia Society's council. He was a member of The Haemophilia Society's Medical Advisory Panel from the

1970s through, it would seem likely, to the early 1990s and, although some of the key documents that we looked at in the Cardiff presentation relating to Professor Bloom during 1983 are authored by Professor Bloom, we know, for example, that at the meeting on 8 October 1983, when Professor Bloom addressed the council in a meeting of the Haemophilia Society on AIDS, Dr Rizza was present at that meeting. The precise role he took in the meeting is unclear.

Sir, I want to turn to consider just briefly a handful of the themes that emerge from the individual witness statements of patients treated at the Oxford Haemophilia Centre or their relatives.

I'm not going to deal with it in detail to or to mention patients by names but just to list themes which will be, I think, well known now to everybody who has been following the Inquiry's history, but these are all themes that emerge from statements relating to Oxford.

The first is non-receipt of information or advice as to the risks associated with treatment with blood products.

A second theme which emerges from a number of the statements is the extent to which patients had

placed their faith and trust in their clinicians at the Oxford Haemophilia Centre treating them.

The third theme that emerges from the Oxford-related statements is the extent to which blood products, factor concentrates were described to patients as being "ground-breaking" or "wonder drugs", presented in highly positive terms.

A fourth theme is absence of knowledge of or consent to being tested for the presence of infections.

A fifth theme is belief of a number of individual witnesses that they had been involved in or enrolled in or the subject of research without their informed knowledge and consent.

A sixth theme is about the manner of diagnosis -- or communication of diagnosis, I should say, with HIV or HCV and, associated with that, a further theme of not receiving sufficient information or advice following diagnosis, or of delay in the communication of the diagnosis.

So, again, common to a number of centres, but statements from individuals treated at Oxford some have identified in their records dates of tests and then identified a delay -- in some cases, quite a significant delay -- before those test results and

the diagnosis is communicated to the patient.

Then a final theme is in relation to the availability of medical records. One individual description from the oral evidence of one witness was a widow who described feeling as though the records of her late husband had been thrown up in the air and then only some of them had been caught. Incomplete records or difficulties in obtaining records was an issue raised by a number of witnesses who gave evidence or who provided statements relating to their treatment at Oxford.

Sir, the final matter I wanted to deal with is to look at some parts of Dr Rizza's expert report produced for the purposes of the HIV litigation.

Henry, it should be at HCDO0000003_001.

It's a long report. We won't go into all of it.

If we go to page 6, please, Henry.

We see here and on the following page a number of the committees, organisations, working parties, et cetera, with which Dr Rizza was involved. I named a number of them in the course of the presentation today.

If we then go, Henry, to page 38. I'm not going to go through the detail of this but there's a section in his litigation report in which Dr Rizza describes

the history of the organisation of haemophilia care in the United Kingdom, and it gives an overview of how designation of haemophilia centres developed, and in particular it helps explain the particularly significant position occupied by Oxford, designated as a special treatment centre at an early stage.

So I won't show any particular part of it on the screen but it provides some useful background.

Then if we go to page 55, please, you will see there a brief section in the report headed "The relative risks of cryoprecipitate and large pool Factor VIII concentrate". In it, Dr Rizza says this:

"With regard to the relative risks of transmission of hepatitis by cryoprecipitate and pooled Factor VIII concentrate it is generally stated that cryoprecipitate since it is prepared from a single donor or a limited number of donors is less likely to transmit hepatitis than Factor VIII concentrate made from a large pool of donor plasma."

He then goes on to say that:

"Unfortunately adequate data are not available to settle the issue."

If we go towards the bottom of this page he says that it can be "difficult to make sound comparisons between Factor VIII concentrate and cryoprecipitate".

Clearly that is an issue you will need to consider in due course but that is Dr Rizza's perspective on the point.

If we go then to page 60, there's a section headed "Hepatitis in haemophiliacs". If you go two pages to page 62, please, Henry, bottom paragraph, this is what Dr Rizza has to say -- and I should say, of course, this, as I hope I made clear earlier, was a report prepared by Dr Rizza for the defendants with HIV litigation:

"During the early to mid-1970s I think it is fair to say that hepatitis was probably not perceived as a long-term problem in haemophiliacs. The incidence as manifest by overt jaundice seemed to be low, the clinical illness was mild and seemed self-limiting in most patients, and death from acute hepatitis seemed very uncommon. More detailed follow-up on haemophiliacs, however, during the late 1970s showed that a significant number of haemophiliacs who were clinically well had persistently abnormal tests of liver function. In particular the blood level of certain liver enzymes were raised above the normal level ..."

He refers to a 1976 and a 1980 study.

"Liver biopsy studies of haemophiliacs with

abnormal liver function tests revealed a significant number with abnormal liver histology consistent with chronic liver disease ..." and refers there to Mannucci '75 and Spero and Preston in '78.

Sir, again, you may wish to consider that and the material that Dr Rizza refers to when you are considering what was or should have been known about the serious nature of hepatitis in the course or the 1970s.

If we look then at page 75, this is the concluding part of a section that's headed "Response of UK Haemophilia Centre Directors to the problem of hepatitis in haemophiliacs", and I just draw attention to what is under the heading "CRR Comment". This is Dr Rizza's comment on a narrative he's set out above:

"From its inception the UK Haemophilia Centre Directors' Organisation was aware of post transfusion hepatitis in haemophiliacs and took steps to study the problem and to be involved in the surveillance of blood products in particular the heat-treated materials when they became available in the early 1980s. Little was known about non-A, non-B hepatitis in 1972 when commercial Factor VIII concentrate became widely available and at first the condition was thought to be mild with little in the

way of long term damage. The studies carried out on haemophiliacs in this country and abroad showed that this was not the case and that significant numbers of haemophiliacs in time went on to develop chronic liver disease."

So again, sir, you will no doubt fit that into your assessment of what was and should have been known at relevant times.

If we go to the next page, please, Henry, this section of Dr Rizza's report is entitled "Recognition of AIDS and development of knowledge", and if we go to the last four lines we can see Dr Rizza saying this:

"By the end of 1982 it was clear that besides promiscuous homosexuals, there were other groups at risk obvious developing AIDS. Those included intravenous drug abusers and recipients of blood transfusions and blood products in particular haemophiliacs."

So there a statement by Dr Rizza that, by the end of 1982, it was clear that the groups at risk of developing AIDS included recipients of blood transfusion and blood products, in particular haemophiliacs.

If we go on to page 84, under the heading "CRR Comment", Dr Rizza makes this observation:

"Most of the early (1981 and 1982) publications on AIDS appeared in MMWR which was an obscure journal and probably unknown to most clinicians dealing with haemophiliacs in UK. In spite of this the UK Haemophilia Centre Directors were aware of the problems by at least 6 September 1982 when the matter was raised at one of the Reference Centre Directors' meetings. I cannot be certain of the circumstances but the matter was probably raised by Dr J Craske a Virologist in PHLS Manchester who may have been aware of the MMWR reports."

So that is Dr Rizza's speculation as to how the matter came to be raised on 6 September, that it was raised by Dr Craske.

If we go to the next page, the top of the page refers to Dr Jane Desforges' editorial in New England Journal of Medicine 13 January 1983, which we have obviously looked at on more than one occasion. Can we go to CRR comment please, Henry. This is what Dr Rizza says:

"This article is the first that I am aware of which gave such strong recommendations concerning the AIDS problem in haemophiliacs. It was noted and discussed but made little impression on clinical practice in UK nor in USA as far as I am aware.

I think this was due in part to the fact that very few haemophiliacs in USA had developed AIDS and none in UK. Also, to have changed to using cryoprecipitate on such a large scale would almost certainly have reduced the quality of treatment of bleeding episodes. It would not have been possible to continue with the home therapy programme as cryoprecipitate is not suitable for home treatment. The perception was that with haemorrhage being the commonest cause of death it would be unreasonable to put the patient at greater risk of haemorrhage in view of the limited information on AIDS and its long term prognosis. The effect of switching to cryoprecipitate would have placed great stress on the Blood Transfusion Service, as Dr Desforges says. Also by using cryoprecipitate prepared by local blood transfusion centres raw material for production of Factor VIII concentrate would have been diverted from plasma fractionation laboratories with the result that research into virus-free fractions would have been slowed down. Moreover, cryoprecipitate although carrying a reduced risk of transmitting AIDS did carry a risk and this presumably was increasing during 1983 and 1984 until testing for HIV in blood donors became available."

So, sir, if we just go back to the previous

page, Henry, we can see awareness of the article in the New England Journal, Dr Rizza says it was noted and discussed. Presumably that's a reference at least to Reference Centre Directors, and we know that of course from the minutes of meetings we've looked at from the London Airport hotel meeting.

Dr Rizza's statement it made little impression on clinical practice may of course be right because the evidence you have heard so far suggests that at least as far as UKHCDO is concerned there were no recommendations at that stage for changes in clinical practice.

The reasons that are given for not changing clinical practice at all at that stage are firstly the statement that very few haemophiliacs had developed AIDS in the US and none in the UK and you no doubt, sir, will wish to consider the adequacy of that explanation.

Then various reasons are given about why a switch to cryoprecipitate would have had disadvantages. The statement beginning, "The perception was that with haemorrhage being the commonest cause of death it would be unreasonable to put the patient at greater risk of haemorrhage", may beg the question for you to answer, sir, as to whose

perception, clinicians or patients?

We do not see in Dr Rizza's report any particular discussion of what information was or was not provided to patients throughout this period.

If we move on, Henry, to page 91, there is reference there halfway down the page to a paper in the journal Science on 20 May 1983. It's said:

"This is an important paper [this is Dr Rizza's comment] and was the first to clearly describe isolation of a retrovirus which might be the cause of AIDS", but the comment then is that the authors themselves are cautious in interpreting their results.

SIR BRIAN LANGSTAFF: This was the paper which gave rise to LAV as what became an alternative label and eventually recognised as the same as HTLV-III.

MS RICHARDS: Yes, that's right. It's certainly one of the papers in May 1983 on that issue.

If we go to page 94, we'll see a theme in the comments, sir. So here we have a reference to September 1983 and the report in MMWR and the comment is:

"This article shows the uncertainty that still existed about the cause of AIDS and highlights to some extent the confusion that existed at the time concerning the findings of Gallo and Barré-Sinoussi

and whether or not the two viruses were the same."

If we go to the following page please, Henry, September -- no, that's just a repetition of the same page, sorry. The document's been poorly copied.

So there is a number of times in this report when Dr Rizza draws attention to what he says is continuing uncertainty about the cause of AIDS.

If we go to page 98 and we get to the bottom to half of the page, December 1983, there's reference to a letter in The Lancet about the prevalence of AIDS in West Germany and the comment of Dr Rizza is there was strong epidemiological evidence by the end of 1983 that AIDS was caused by a transmissible agent, probably a virus.

Then he says:

"Haemophilia experts in USA and UK [the haemophilia experts in the UK are presumably Dr Rizza, Professor Bloom and other Reference Centre Directors primarily] were recommending that severely affected haemophiliacs should continue to use Factor VIII concentrate as the perceived dangers of haemorrhage were greater than those of AIDS. For mildly affected patients cryoprecipitate or DDAVP was recommended ... for children cryoprecipitate was recommended where practicable."

He refers to recommendations issued in the States.

If we go then to page 101, reference in the bottom half of the page to an article in Nature by Robin Weiss and the comment below is that, I think this is referring to a number of the papers, but:

"The paper is important, this along with a paper by Barré-Sinoussi et al show convincingly that a virus was the cause of AIDS."

So again the comments to some extent are a search for evidence or proof and that's the conclusion set out at the bottom of that page.

If we go to page 105 we then see reference 29 September 1984 to an article in The Lancet which describes adding a mouse retrovirus to cryoprecipitate from which freeze-dried Factor VIII was then made. Dr Rizza's comment is this was an important paper in that it stimulated the change to heat-treated Factor VIII and was thought to provide sufficient evidence to warrant the change. He identifies questions left unanswered. So that is what is said to be sufficient to justify a move to heat-treated products.

If we go on to page 130 this is a section of Dr Rizza's report entitled response of UK Haemophilia

Centre Directors to appearance of AIDS in haemophiliacs. If we go to 131 we can see the entry for November 1982, which refers to a letter that Dr Craske wrote to Dr Rizza. The comment is by the end of 1982, approximately five months after the first report of AIDS in haemophiliacs in USA all UK Haemophilia Centre Directors had been informed of the problem and efforts were being made to obtain up-to-date information and to set up a system of surveillance of haemophiliacs in UK.

Sir, two issues that arise from that for your consideration in due course. One is: is that an accurate description of what had been done by the end of 1982 and was it the appropriate response to what was known by the end of 1982?

We then go please to page 134. There is a detailed comment by Dr Rizza on the decision to continue using imported Factor VIII in May 1983 and if we go to the bottom of that page, Dr Rizza sets out three options:

"1. Stop using imported concentrate and switch to cryoprecipitate or NHS Factor VIII.

"2. Stop using both imported and NHS concentrate and use cryoprecipitate.

"3. Stop all treatment with blood products

including cryoprecipitate."

Sir, you will no doubt wish to consider whether there were in fact potentially other options or combinations of options but Dr Rizza then sets out his own assessment of the options. He says:

"The last ... was quite unacceptable ..."

Again, the question that may arise: to whom?

"... as it would have exposed the patient to the risks of prolonged and uncontrolled bleeding, severe pain and crippling and possibly death."

He describes, at the top of the next page, what he says would have been the impact on the quality of life of the patient and family if there had been a cessation of all treatment with blood products and, at the end of that first paragraph, says this:

"I believe that most patients and in particular the parents of young patients would have found this unacceptable."

Again, sir, the question that obviously arises is the extent to which any attempt was made to actually elicit the views of patients or the parents of young patients.

"Option 1 ..."

He goes on to say, which was a switch to cryo or NHS Factor VIII:

"... was dependent on there being sufficient supplies of the alternative materials ..."

He says that NHS Factor VIII was in extremely short supply in '83 and then says this of cryoprecipitate:

"[It] had been used less and less since the early 1970s when imported concentrate became available. It might have been possible and with great difficulty to switch all patients to cryoprecipitate but cryoprecipitate had several important drawbacks."

Then he sets them out:

"... difficult to reconstitute; several packs had to be pooled ... great variability in its Factor VIII content; allergic reactions were commoner than with Factor VIII concentrate ... unsuitable for home treatment and patients would need to attend hospital ..."

Then he says:

"... as time passed and AIDS spread more widely in the donor population cryoprecipitate would have become less safe."

He then says:

"In practical terms the problem of handling large numbers of doses of cryoprecipitate rapidly and safely would have been very great at most Haemophilia

Centres. In 1983 a large Centre such as that at Oxford was using approximately 7 [million] units of Factor VIII to treat its haemophilia patients. To provide this as cryoprecipitate would have meant handling approximately 100,000 bags of cryoprecipitate per year, or more than 250 bags per day. This would have been extremely difficult to do. Smaller Centres of course might have managed."

Then he says whether or not blood transfusion centres could have provided the cryoprecipitate is a moot point, top of the next page:

"Production of raw plasma would have had to increase two to three fold. Also a switch completely to cryoprecipitate would have resulted in the Blood Transfusion Centres not sending plasma to BPL to fractionation so that development and large scale production of safe NHS concentrates would have been delayed ..."

Then this:

"Finally and not least few patients given the lack of knowledge of AIDS and its implications were prepared to modify their treatment and life routine to such an extent."

So that is a statement by Dr Rizza that patients were not -- it doesn't say "would not have been" --

were not prepared to modify their treatment to the extent of receiving cryoprecipitate rather than concentrate. Thus far, sir, on the evidence the Inquiry has received, I don't recall yet evidence from any patient saying that the alternative of switching completely to cryoprecipitate was discussed with them, but that clearly is a matter that will need to be looked at further.

Then he goes on to talk about:

"The decision to recommend using NHS Factor VIII or cryoprecipitate in children and infrequently transfused or mildly affected patients if that had been the Directors practice was reasonable at the time ..."

About eight to nine lines further down, perhaps a bit further, he says:

"The decision to continue using imported concentrate was reasonable in view of the perceived balance of risks at that time between the dangers of untreated bleeding and the dangers of contracting AIDS."

So that's Dr Rizza's reasoning in relation to the decision to continue using commercial concentrates in May 1983.

If we go to page 140, this is where we reach,

now, December 1984 and the provision of guidelines by UKHCDO in December of 1984.

Just draw your attention to the bottom part of the page, where Dr Rizza says:

"The recommendations ..."

So that's the AIDS advisory document dated 14 December:

"... were sent out shortly after the date on the document but may well have been delayed by postal problems at Christmas. The document would have been received by the Director at the latest during the first week of January 1985."

He then has a comment about the recommendation to use heat-treated concentrates.

If we go to the next page, about ten lines down he says:

"It must be stated that there was a good deal of uncertainty about the safety of heated products in clinical practice."

He talks about the difference of opinion as to the comparative safety of unheated NHS Factor VIII and heated American Factor VIII.

Those are, I think, perhaps the key passages in Dr Rizza's report that I wanted to show you. Clearly, the report itself needs to be read in full and, if it

turns out to be the case that Dr Rizza gives evidence, then no doubt he can be asked further questions about it.

Sir, that I think effectively concludes today's presentation. We've identified in the written note that has been provided to Core Participants and legal representatives a number of issues that you may wish to consider in relation to the Oxford Haemophilia Centre once you have all the available evidence, including potentially any statements you receive from clinicians and further statements from patients.

Some of the key questions that we have identified that you may wish to consider are as follows: What was the centre's and in particular Dr Rizza's state of knowledge about the risks of infection associated with blood products and how did that knowledge develop over time?

Did the centre, including Dr Rizza as its director, underestimate the potential seriousness of non-A, non-B hepatitis? And, if so, why?

When did the centre, and in particular Dr Rizza as director, first appreciate the risks of developing AIDS in consequence of the use of factor products?

What steps did the centre and Dr Rizza as its director take in response to that risk? Were they

sufficient? Should more have been done and if so what?

What influence did Dr Rizza have on the actions and decisions of UKHCDO? Should UKHCDO have provided different or earlier advice to centre directors and, if so, what?

What information and advice was provided by clinicians at the centre to patients about the risks, benefits and disadvantages of treatment with factor concentrates; the availability, suitability and safety of alternatives; the risks of and seriousness of hepatitis, and the risks of and seriousness of HIV and AIDS?

What were the arrangements for testing for HIV and for HCV and were patients told they were being tested? Was their consent sought? How and when were patients informed of the test results? Was appropriate and adequate information provided to them?

How was the care and treatment of those diagnosed with HIV or HCV managed at the centre?

Finally, did the centre provide to patients, who participated in one or more of the multiple research studies undertaken there, sufficient information to enable them to give informed and valid consent?

Core Participants have also suggested a further

issue (and this will arise across the board, not specifically to Oxford or not to Oxford alone) about the position in relation to suspect batches particularly in the later part of 1984 and early 1985 and what protocols or procedures existed in relation to suspect batches and the recall of batches.

Sir, that completes the presentation on Oxford for the week.

SIR BRIAN LANGSTAFF: Thank you very much, Ms Richards. That concludes the work for this week. We are not meeting next week.

MS RICHARDS: No.

SIR BRIAN LANGSTAFF: So the week after we begin on the Tuesday, do we?

MS RICHARDS: We begin on the Tuesday, the date of which temporarily escapes me, with the evidence of Professor Christine Lee on the Tuesday and Wednesday and then the evidence of Professor Edward Tuddenham on the Thursday. Those are witnesses who are giving evidence in person here and obviously will focus upon the Royal Free Hospital.

SIR BRIAN LANGSTAFF: Yes. For those of you who are coming back, I look forward to seeing you again. Those who are not, may I just hope that you stay safe and take care and no doubt I will see you in due

course. But thank you for your attendance. Thank you, Ms Richards, and my thanks to those who represent the various Core Participants who have sat behind you and, no doubt, downstairs. Thank you all until a week -- or Tuesday week is the best way of putting it.

(4.24 pm)

(Adjourned until Tuesday, 20 October 2020 at 10.00 am)

I N D E X

Presentation by MS RICHARDS 1

MS RICHARDS: [39] 1/4 2/17 8/7 11/14 18/17 18/22 35/8 35/13 38/15 42/1 42/9 42/15 47/20 48/14 48/22 49/5 53/4 54/19 54/25 71/4 71/16 75/23 76/3 76/11 77/7 77/11 97/2 99/24 110/19 134/2 136/5 144/24 145/3 145/10 145/15 148/6 161/16 172/12 172/15

SIR BRIAN LANGSTAFF: [40] 2/15 8/4 11/12 18/14 18/18 35/5 35/9 38/14 41/20 42/8 42/11 47/17 48/5 48/18 49/1 53/2 54/11 54/20 70/16 71/14 75/16 75/24 76/7 77/3 77/10 96/21 97/1 99/18 110/8 133/25 136/4 144/21 144/25 145/8 145/12 148/1 161/13 172/9 172/13 172/22

THE WITNESS: [1] 96/23

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'60s [1] 1/6
'69 [2] 11/13 62/10
'70s [1] 61/18
'73 [1] 18/20
'74 [4] 11/13 52/25 53/1 62/11
'75 [1] 156/4
'76 [1] 47/18
'76/'77 [1] 47/18
'77 [2] 11/12 47/18
'78 [1] 156/4
'80 [1] 3/16
'80s [1] 86/6
'83 [1] 166/4
'91 [2] 131/17 136/8
'Case [1] 68/15
'dry [2] 104/13 104/22
'Hemofil [1] 104/12
'Hemofil HT' [1] 104/12
'hepatitis [2] 96/8 104/4
'Intermediate [1] 10/23
'phoned [1] 64/15
'run [1] 114/8
'run-in' [1] 114/8
'Unnatural' [1] 125/8
'virgin' [1] 102/22

.

... [5] 39/8 57/16 138/19 162/24 165/6
... an [1] 57/16

0

0000002 [1] 36/14
001 [7] 64/1 83/5 103/2 103/10 130/22 136/6 153/15
002 [10] 33/10 43/2 82/17 83/2 102/15 128/21 130/10 133/3 135/5 141/23
003 [3] 109/20 113/14 133/12
005 [4] 34/1 72/22 127/23 129/12
006 [2] 80/4 138/13
007 [4] 68/11 77/12 118/6 124/7
010 [2] 71/17 142/23
014 [1] 120/23
015 [1] 100/6
018 [1] 108/3
019 [1] 107/22
020 [1] 106/25
024 [1] 71/24
036 [2] 34/10 149/13
042 [1] 87/23
044 [1] 94/25
049 [1] 58/17
052 [1] 24/2
053 [1] 22/14
062 [1] 38/19
076 [1] 121/22
080 [1] 15/21
098 [1] 21/6

1

1 March [2] 90/13 92/8
1 million [1] 56/15
1 October [1] 139/9
1 September 1991 [1] 133/7
1,000-4,000 litres [1] 11/2
1,179 [1] 121/13
1,426 [1] 101/11
1.01 pm [1] 99/21
1.54 per cent [1] 15/18
10 [1] 12/19
10 May 1984 [1] 103/11
10.00 [2] 1/2 173/8
10.12.84 [1] 107/5
100 [1] 119/22
100 per cent [1] 96/2
100,000 [1] 167/5
100,000-odd [1] 21/15
101 [1] 163/3
105 [2] 93/9 163/13
109 [2] 116/23 118/11
109 haemophilia [2] 112/9 116/7
11 [1] 62/11
11 January 1982 [1] 87/25
11 January 1983 [1] 88/1
11 July [1] 131/17
11 May [1] 68/12
11.04 [1] 42/13
11.35 [1] 42/12
110 [1] 78/2
12 [2] 31/5 52/10
12 December 1972 [1] 43/3
12 July 1977 [1] 24/3
12 months [1] 16/11
12 November 1980 [1] 58/18
13 [1] 158/17
13 April 1982 [2] 141/24 141/25
13 December 1984 [1] 107/2
13 July [1] 77/5
13 March 1984 [1] 102/18
13 May [1] 71/20
13 per cent [1] 13/3
13 September 1990 [1] 138/14
130 [1] 163/24
131 [1] 164/2
134 [1] 164/16
135 [1] 129/18
13th [1] 74/14
14 [2] 117/15 129/19
14 December [1] 169/7
14 December 1984 [1] 85/25
140 [1] 168/25
15 [3] 48/20 120/18 129/22
15 December 1982 [1] 86/20
15,000 [1] 18/6
16 November 1983 [1] 83/6
16 years [1] 97/19
16,000 [1] 19/16
17 April 1989 [1] 124/8
17 July 1991 [1] 128/22
17,623 [1] 14/15
17.74 per cent [1] 15/7
18 [2] 53/9 120/12
18 December [1] 59/9
18 July 1972 [1] 16/8
18 March 1991 [1] 140/3
19 [1] 30/22
19 February 1973 [1] 18/19
19 January [3] 65/14 67/17 68/1
19 January 1983 [1] 65/17
1960s [4] 7/16 31/14 60/11 141/19
1967 [7] 4/22 38/22 40/12 41/14 42/16 55/19 143/4
1968 [1] 2/23
1969 [4] 3/13 9/23 14/25 60/20
1970 [4] 6/22 7/1 7/4 9/14
1970s [15] 16/5 19/17 29/5 30/23 42/3 59/16 60/12 61/6 62/5 101/14 151/1 155/11 155/19 156/9 166/7
1971 [7] 12/14 14/8 14/10 14/21 17/3 33/6 60/20
1972 [19] 13/3 16/8 18/12 24/7 26/1 26/20 29/5 30/23 37/24 38/1 38/21 42/19 43/3 43/10 62/13 62/16 62/25 148/14 156/23
1972/3 [1] 52/1
1973 [9] 15/7 18/19 19/6 19/22 21/5 24/7 45/2 45/20 49/25
1973/1974 [1] 55/1
1974 [10] 3/16 9/23 12/10 13/3 15/1 21/15 55/1 55/4 55/24 60/18
1975 [7] 5/13 14/10 14/13 14/22 33/7 33/11 137/7
1976 [5] 15/13 16/1 34/2 57/23 155/24
1977 [13] 3/20 4/23 9/22 11/8 22/13 22/15 24/3 25/5 25/18 34/11 60/7 143/6 143/7
1979 [1] 3/13
1980 [7] 36/21 37/1 58/13 58/18 59/9 111/21 155/24
1980-85 [1] 117/2
1980-86 [1] 118/14
1980-87 [1] 121/12
1980s [5] 59/16 127/20 147/20 150/20 156/22
1981 [2] 37/3 158/1
1982 [16] 63/13 64/2 65/6 86/20 87/25 100/7 141/24 141/25 157/13 157/20 158/1 158/6 164/3 164/5 164/14 164/15
1983 [34] 4/6 65/17 68/10 68/12 71/18 72/20 73/21 74/1 77/12 79/15 80/2 81/16 83/6 83/7 83/18 84/1 88/1 90/3 90/7 90/13 92/4 99/14 151/4 151/6 158/17 159/23 161/7 161/17 161/20 162/9 162/12 164/18 167/1 168/24
1983/1984 [1] 103/19
1984 [21] 36/20 85/22 85/25 102/18 103/11 103/19 103/21 104/1 106/10 106/10 106/15 106/16 107/2 108/4 110/10 127/13 159/23 163/14 169/1 169/2 172/4
1985 [21] 108/21 109/17 110/22 111/17 112/9 113/13 114/20 114/22 115/15 115/17 115/22 116/2 116/14 117/8 117/12 117/15 117/16 119/23 127/10 169/12 172/4
1986 [9] 113/16 115/18 116/19 116/21 116/24 117/15 117/16 121/16 142/24
1987 [7] 3/20 4/9 4/10 118/5 118/7 118/13 118/19
1988 [9] 115/22 118/10 120/24 121/25 122/7 123/6 123/7 123/9 125/5
1989 [5] 123/25 124/8 127/24 129/12 130/9
1990 [5] 4/9 4/10 135/8 135/24 138/14
1990s [5] 1/7 1/9 2/24 147/17 151/2
1991 [12] 128/22 129/10 130/11 130/23 133/7 133/13 135/9 136/9 136/11 136/24 139/19 140/3
1992 [1] 5/13
1993 [1] 4/24
1998 [1] 31/4

2

2 million [1] 57/7
2 o'clock [1] 99/20
2,000 [1] 17/10
2,504 [1] 101/12
2,570 patients [1] 116/15
2.00 pm [1] 99/23
20 [3] 100/25 111/17 131/4
20 December 1984 [1] 110/10
20 February 1973 [1] 45/2
20 March 1973 [1] 45/20
20 May 1983 [1] 161/7
20 October 2020 [1] 173/8
20 per cent [2] 48/21 129/6
20 years [1] 137/13
200 [2] 10/24 52/14
2020 [2] 1/1 173/8
21 [1] 53/10
21 March 1991 [1] 139/19
21 October 1988 [1] 120/24
21.99 per cent [1] 15/2
22 March [2] 18/20 93/10
22 September 1986 [1] 142/24
23 August [2] 136/9 136/11
23 August 1984 [1] 127/13
23 August 1990 [1] 135/8
23 May [1] 73/7
23 September 1982 [1] 100/7
23,041 [1] 19/12
24 [1] 21/20
24 January [1] 68/3
24 January 1983 [1] 90/7
24 July 1989 [1] 127/24
24 June 1983 [1] 72/20
25 June 1991 [1] 130/23
25 per cent [1] 33/7
250 [1] 47/17
250 bags [1] 167/6
250,000 [1] 29/23
250-300 [2] 35/24 36/1

2

2500 [1] 11/5
27 [1] 121/14
27 January 1988 [1] 121/25
27 October 1972 [1] 26/1
27 September 1985 [1] 116/2
28 December 1984 [1] 108/4
29 January 1988 [1] 118/10
29 July [1] 79/5
29 July 1983 [1] 77/12
29 March 1984 [1] 104/1
29 September 1984 [1] 163/14
2900 [1] 143/9

3

3 October 1983 [1] 81/16
3 October 1986 [1] 116/19
3 September [1] 136/8
3,545 [1] 121/11
3.14 pm [1] 148/3
3.45 [1] 148/2
3.45 pm [1] 148/5
3.86 per cent [1] 15/2
30 [1] 91/6
30 January [1] 109/21
30 July 1986 [1] 113/16
30 May 1975 [1] 137/7
30 patients [1] 95/14
30,000 [3] 19/13 20/14 21/15
300 [2] 35/24 36/1
33,400 [1] 14/8
333 [1] 120/5
35.25 per cent [1] 15/8
379 [1] 129/4
38 [1] 153/23
39 [1] 129/6

4

4 July 1977 [1] 22/15
4 months [1] 129/22
4,500 [1] 78/6
4-6 [1] 113/25
4.24 pm [1] 173/7
40 patients [1] 98/19
40 per cent [1] 100/25
400 [1] 11/4
42 [1] 50/21
42.61 per cent [1] 15/14
43 [1] 31/9
43 per cent [1] 12/13
45.93 per cent [1] 15/4
4th [1] 24/5

5

5 year [1] 14/9
5.3 per cent [1] 120/12
50 donor [1] 97/8
50 per cent [1] 114/4
50,000 [2] 20/24 39/21
500 [1] 91/10
500,000 [1] 29/24
50s [1] 8/11
52 weeks [1] 98/2
53 [1] 120/21
54 [2] 14/13 14/22
55 [1] 154/9
55.85 per cent [1] 15/16
57 per cent [1] 129/5

6

6 July 1983 [1] 74/1
6 per cent [2] 48/16 48/19
6 September [1] 158/13
6 September 1982 [2] 63/13 158/6
60 [3] 111/17 130/5 155/4
60.89 per cent [1] 15/4
60s [1] 9/14
61 [1] 129/5
62 [1] 155/6
63 [2] 106/13 149/16
63 per cent [1] 129/4
64 [1] 149/23
664 [1] 19/5

7

7 February [1] 45/6
70s [2] 9/14 61/25
74 per cent [1] 116/8
75 [1] 156/10
750 [2] 10/25 47/18
78 haemophiliacs [1] 120/14
78 partners [1] 120/13

8

8 November [1] 83/7
8 October 1982 [1] 64/2
8 October 1983 [1] 151/6
8 products [1] 105/21
80 per cent [1] 12/11
800 [1] 46/21
81 [2] 116/8 120/21
83 replies [1] 112/10
84 [1] 157/24
84 centres [1] 117/12
85 [1] 117/2
86 [2] 118/14 119/23
87 [1] 121/12
8p [1] 35/20
8Y [10] 113/20 113/20 113/22 114/6 114/11 114/15 114/21 115/9 115/15 115/20

9

9 July [1] 117/7
9 June 1989 [1] 129/12
9 March 1983 [1] 92/4
9 October 2020 [1] 1/1
9 patients [1] 95/20
91 [1] 161/5
94 [1] 161/18
98 [1] 162/8
991 [1] 131/12

A

A1 [1] 143/17
A7 [1] 143/17
A8 [1] 143/21
Abbot [1] 34/19
ability [3] 15/11 48/1 56/18
able [5] 18/12 25/12 88/18 126/7 127/5
abnormal [5] 104/25 134/11 155/21 156/1 156/2
abnormalities [5] 5/22 5/25 61/23 80/22 134/10
abnormality [2] 81/21 82/23
about [150] 2/3 7/21 8/14 11/4 12/4 13/17 16/19 17/2 18/6 18/7 19/4 20/2 22/17 23/9 25/2 26/8 26/11 26/14 26/17 26/18 27/19 28/2 28/13 28/19 29/14 30/23 31/13 32/14 32/16 32/19 32/22 33/7 35/15 35/20 36/20 37/16 39/21 39/23 42/22 44/1 45/7 46/21 47/1 48/15 48/20 49/25 50/23 51/4 51/23 52/9 52/14 53/3 53/5 53/8 53/23 54/7 54/10 54/21 57/11 61/15 61/18 62/10 62/14 63/1 63/17 65/6 67/19 67/20 70/23 71/11 73/14 73/17 74/4 74/8 76/23 78/24 79/7 79/15 79/19 81/4 84/9 84/24 85/4 85/5 85/6 85/10 85/20 86/1 88/9 91/5 91/21 93/14 100/4 100/15 101/21 108/6 108/10 108/20 111/13 111/19 113/10 117/14 118/1 119/25 120/4 121/17 122/7 122/16 123/20 127/7 131/14 131/23 132/20 136/25 137/2 138/7 138/9 140/22 141/11 142/19 144/12 144/18 145/15 145/18 147/3 147/14 147/17 147/23 148/15 148/19 148/22 149/3 149/4 152/15 156/7 156/22 160/19 161/23 162/7 162/10 168/9 168/15 169/13 169/15 169/18 169/20 170/2 170/15 171/8 172/2
above [9] 8/5 37/18 68/16 114/9 115/11 125/2 146/22 155/23 156/15
abroad [4] 41/3 108/15 150/9 157/2
absence [3] 59/21 102/6 152/8
absences [1] 137/13
absolutely [5] 23/17 35/2 35/8 55/14 109/2
abuse [1] 145/16
abusers [1] 157/16
accelerate [1] 41/8
accept [1] 92/21
accepted [1] 126/6
access [2] 31/23 98/16
accident [2] 64/25 124/25
account [1] 38/4
accounted [1] 12/11
accurate [4] 77/3 101/1 101/20 164/13
achievable [1] 32/2
achieve [3] 41/15 41/25 45/16
acquired [3] 64/9 65/24 148/12
across [5] 111/4 122/3 133/1 138/2 172/1
act [3] 68/22 125/5 147/15
action [3] 67/21 85/17 107/14
actions [1] 171/3
activities [3] 3/22 94/17 125/10
activity [4] 35/20 50/3 53/14 53/15
actually [6] 21/22 24/17 58/9 73/1 126/5 165/21
acute [9] 5/18 64/6 98/5 99/4 100/10 100/18 100/23 101/18 155/16
added [1] 135/19
adding [1] 163/15
addition [3] 14/17 69/9 118/18
additional [1] 110/15
addressed [6] 16/9 19/10 83/6 123/10 123/10 151/7
addresses [1] 35/9
adds [2] 58/5 101/25
adequacy [1] 160/17
adequate [7] 44/5 55/14 56/13 56/16 94/8 154/21 171/18
adequately [1] 57/5
adhere [1] 94/11
Adjourned [1] 173/8
Adjournment [1] 99/22
adjusted [1] 15/24
administered [3] 20/21 66/11 113/2
administering [1] 88/23
administration [1] 52/4
administrations [1] 93/2
administrative [1] 5/5
adolescents [3] 37/12 38/7 69/21
adopt [1] 55/6
adults [2] 2/12 66/18
advance [2] 46/3 89/14
advances [1] 126/16
advantage [2] 9/7 17/14
advantages [1] 50/2
advice [8] 76/15 76/20 122/22 137/12 151/22 152/19 171/5 171/7
advise [3] 19/15 30/18 45/4
adviser [1] 4/2
advisory [5] 4/7 85/25 122/12 150/25 169/6
advocate [1] 38/18
affect [1] 54/4
affected [16] 14/1 14/10 37/13 47/6 54/14 72/14 90/21 91/10 91/21 91/23 92/9 103/15 139/7 162/19 162/22 168/12
afraid [1] 93/7
after [22] 7/20 42/1 64/2 64/15 74/3 85/5 95/21 96/4 99/4 100/24 101/18 106/12 107/1 121/16 132/16 137/13 137/13 141/2 147/13 164/5 169/8 172/13
AG [2] 17/9 18/5
again [43] 8/16 11/21 21/24 22/16 23/10 28/12 31/10 35/25 37/3 38/1 48/7 53/23 55/2 58/20 60/10 65/10 67/9 68/25 79/22 80/1 81/11 83/8 83/13 84/3 85/13 85/19 86/1 88/2 88/5 98/24 104/2 118/9 120/7 128/5 138/1 149/2 152/21 156/5 157/6 163/10 165/7 165/19 172/23
against [2] 17/21 83/20
age [2] 82/3 97/19
agenda [2] 86/25 133/6
agent [3] 66/14 111/20 162/13
agents [2] 35/12 35/14
ago [4] 26/20 41/21 43/10 132/15
agree [6] 21/14 73/18 89/15 92/9 128/16 139/5
agreed [5] 72/11 73/16 82/6 107/9 130/6
agreeing [1] 55/23
agreement [5] 30/15 33/17 57/13 84/9 84/20
agrees [2] 67/15 94/10
ahead [1] 45/3
AHF [1] 49/18
AHG [8] 7/21 8/9 8/9 8/10 16/13 16/16

A

AHG... [2] 16/18 46/18
AIDS [89] 4/8 4/10 4/12 36/24 63/8 63/11 63/17 64/7 64/19 65/24 66/4 66/13 67/4 67/16 68/9 68/14 68/19 69/11 70/11 74/15 74/22 74/25 75/10 75/20 76/1 77/15 77/17 78/3 78/5 78/15 78/20 78/25 83/25 84/6 84/8 85/11 85/14 85/25 105/19 107/6 110/11 111/15 120/21 121/6 121/6 121/18 121/24 122/3 122/6 122/11 129/13 129/19 129/20 130/3 138/24 144/14 144/15 144/23 145/6 145/17 146/20 146/22 149/20 150/8 151/8 157/11 157/15 157/21 158/2 158/23 159/2 159/12 159/22 160/16 161/11 161/23 162/7 162/10 162/13 162/22 163/9 164/1 164/6 166/19 167/21 168/21 169/6 170/23 171/13
AIDS congress [1] 77/15
AIDS-related [1] 144/15
AIDS/3 [3] 144/23 146/20 146/22
aim [2] 45/15 48/2
aimed [1] 109/21
aims [2] 68/18 81/20
air [2] 65/3 153/6
Airport [3] 68/3 90/7 160/6
al [2] 67/7 163/8
albeit [2] 41/23 126/23
alerted [1] 75/24
alerting [2] 76/3 76/4
all [72] 5/8 10/14 11/21 12/11 12/25 13/4 13/10 14/5 19/18 20/18 21/13 31/13 35/17 35/18 35/19 36/8 46/12 51/7 56/22 58/20 66/6 72/23 73/18 77/1 78/2 78/7 78/14 79/10 82/8 82/10 88/19 91/7 91/17 92/11 94/1 94/5 94/16 95/20 96/3 98/14 99/9 104/2 105/16 107/9 107/11 110/4 113/23 114/6 116/13 119/18 120/14 120/18 123/17 124/22 126/5 135/18 135/18 138/12 138/24 142/8 143/14 145/8 146/5 151/19 153/16 160/14 164/6 164/25 165/14 166/9 170/9 173/4
allergic [1] 166/14
allied [1] 23/7
allocated [1] 28/10
allocating [1] 17/22
allocation [7] 20/3 20/6 20/25 21/3 21/4 22/22 23/4
allocations [1] 57/8
allow [3] 21/1 22/1 29/9
allowing [1] 21/16
almost [4] 22/8 135/8 149/23 159/4
alone [3] 13/1 17/19 172/2
along [4] 27/4 64/20 89/3 163/7
alongside [1] 63/23
Alpha [1] 104/22
already [11] 11/20 23/2 28/25 42/16 59/24 64/19 72/17 98/21 106/15 107/15 128/2
also [30] 1/18 2/21 22/19 34/25 39/9 59/12 60/23 69/11 72/10 72/11 74/21 79/7 91/21 94/9 101/21 108/24 111/24 112/1 120/13 123/11 128/11 135/19 142/7 142/19 145/19 150/21 159/3 159/15 167/13 171/25
alternative [6] 17/23 114/10 139/5 161/14 166/2 168/5
alternatives [1] 171/11
although [13] 24/21 34/4 35/20 71/21 72/23 88/16 89/12 91/10 119/12 126/15 127/3 151/2 159/21
always [10] 8/1 23/8 24/8 37/11 38/5 44/1 52/19 91/2 125/20 139/10
am [22] 1/2 21/13 21/16 37/21 42/13 43/6 55/11 68/17 74/23 74/25 75/18 114/8 115/11 125/15 125/18 130/15 130/25 131/9 138/20 158/21 158/25 173/8
Ambulance [4] 139/22 139/25 140/21 140/22
amendments [1] 144/11
America [2] 65/7 111/23
American [9] 37/2 37/4 37/5 37/8 41/2 69/9 75/1 111/17 169/22
Americans [1] 67/2
among [2] 47/5 53/21
amongst [4] 47/23 95/15 97/5 124/21
amount [19] 12/7 12/20 13/7 14/3 14/12 16/18 20/14 23/25 29/16 29/19 29/21 34/5 34/7 41/3 50/4 110/3 110/13 142/7 143/17
amounts [10] 10/1 37/15 37/23 40/5 43/21 51/17 53/7 55/14 56/12 69/11
ample [2] 16/3 60/7
ampoules [2] 35/23 35/25
anaemia [1] 129/25
analysed [4] 99/11 141/17 142/9 143/6
analyses [1] 86/4
analysing [4] 5/5 115/24 129/3 141/6
analysis [7] 1/24 60/21 119/14 141/14 143/2 146/25 148/18
animal [3] 7/9 8/9 8/10
animals [2] 92/17 92/25
annual [9] 5/6 57/6 141/15 141/18 142/10 142/12 142/13 142/15 142/19
annually [4] 20/14 20/25 29/23 29/25
annum [2] 14/4 18/6
anonymous [1] 119/8
another [15] 1/25 10/18 17/21 21/10 43/22 52/5 53/18 61/9 64/20 78/19 79/22 98/15 108/11 126/4 150/19
answer [3] 124/16 132/8 160/25
answers [1] 134/18
anti [22] 7/8 7/10 48/15 54/13 114/16 116/21 117/4 118/7 118/16 118/25 120/4 127/11 127/13 128/12 129/7 131/25 132/2 132/4 132/7 136/12 136/16 144/19
anti-Factor VIII [2] 48/15 54/13
anti-haemophilic [2] 7/8 7/10
anti-HCV [6] 129/7 131/25 132/2 132/4 132/7 136/12
anti-HIV [12] 114/16 116/21 117/4 118/7 118/16 118/25 120/4 127/11 127/13 128/12 136/16 144/19
antibodies [6] 48/15 54/13 60/17 60/20 142/6 148/12
antibody [13] 111/20 116/3 116/6 120/6 120/14 120/16 120/18 121/13 122/10 129/18 132/1 133/16 133/17
anticipate [1] 1/23
antigen [2] 17/16 46/23
antigens [1] 148/12
anxious [2] 45/8 130/25
any [43] 8/22 22/5 23/17 28/7 29/9 35/14 54/18 55/12 61/8 64/13 65/1 66/4 67/24 69/1 69/4 72/8 74/16 75/8 77/1 83/20 85/17 91/16 92/25 93/21 93/23 94/13 94/16 96/12 96/18 97/6 102/1 110/18 128/9 128/13 129/3 134/22 140/8 148/9 154/7 161/2 165/20 168/5 170/10
anyone [1] 73/17
anything [1] 76/9
anyway [2] 54/16 108/22
anywhere [1] 134/23
Apart [1] 92/23
apologies [2] 19/5 37/19
apparatus [1] 40/22
apparent [3] 36/9 109/16 124/11
apparently [2] 26/10 64/21
appear [8] 76/19 81/11 98/23 123/8 135/3 139/23 147/19 148/20
appearance [1] 164/1
appeared [1] 158/2
appearing [1] 111/24
appears [15] 4/16 5/10 6/4 15/16 28/13 33/14 36/10 80/25 97/13 98/12 108/1 120/24 124/19 126/23 148/15
application [1] 87/12
applied [1] 27/25
appreciate [1] 170/22
apprehension [2] 65/3 68/20
approach [2] 67/25 69/1
approached [1] 130/6
approaches [1] 93/23
approaching [1] 131/4
appropriate [6] 55/5 77/19 109/10 149/8 164/14 171/18
approval [2] 137/21 141/8
approximately [3] 164/5 167/2 167/5
April [7] 25/5 79/14 108/21 111/17 124/8 141/24 141/25
April 1985 [2] 108/21 111/17
Arblaster [2] 27/2 27/24
are [191]
area [6] 2/14 2/21 19/20 122/3 124/2 150/18
areas [2] 2/22 29/9
argument [1] 23/8
arguments [1] 57/12
arise [3] 164/11 165/7 172/1
arisen [1] 140/21
arises [3] 46/18 56/4 165/19
Armour [2] 34/20 104/21
Armour's [1] 106/11
Aronstam [2] 27/2 27/24
around [7] 19/22 49/6 80/6 98/14 127/20 133/4 142/9
arranged [2] 94/3 94/9
arrangements [8] 73/3 81/5 86/2 86/19 121/19 128/8 139/14 171/14
arranging [1] 71/19
Arthur [4] 74/12 75/21 75/22 75/24
Arthur Bloom [2] 74/12 75/22
Arthur's [2] 74/23 75/18
article [6] 9/22 158/21 160/1 161/22 163/4 163/14
articulated [1] 38/12
as [220]
ascertain [1] 90/25
ascertained [1] 97/23
aside [1] 61/7
ask [8] 18/5 30/15 32/14 36/13 71/16 82/14 83/13 144/1
asked [18] 1/13 20/10 28/4 32/4 67/8 74/12 76/13 85/13 93/22 107/25 117/3 117/6 117/22 118/15 118/23 136/19 144/18 170/2
asking [10] 19/1 34/13 43/11 53/8 54/10 63/16 64/17 74/24 75/19 131/23
asks [4] 128/1 128/11 143/22 144/15
aspect [2] 59/20 141/13
aspects [2] 3/4 60/16
assembling [1] 45/4
assess [9] 29/16 50/2 69/3 70/11 81/1 83/19 96/7 110/1 112/7
assessed [1] 91/22
assessment [5] 91/25 95/2 95/10 157/7 165/5
assessments [1] 92/14
assist [1] 9/11
assists [1] 79/22
Associate [1] 5/10
associated [8] 17/16 66/17 67/4 80/22 145/6 151/22 152/17 170/16
association [2] 63/10 74/15
assumed [1] 112/25
assumes [1] 147/21
assuming [1] 126/9
assurance [1] 139/24
assure [1] 92/11
assured [1] 92/18
Atlanta [1] 66/2

A

attack [4] 96/2 99/4 100/23 104/14
attempt [6] 29/15 50/1 80/25 83/18 88/11 165/20
attempts [1] 101/23
attend [7] 5/19 39/17 72/2 77/14 77/19 126/6 166/16
attendance [1] 173/1
attendants [1] 68/21
attended [4] 40/1 65/13 85/23 106/10
attendees [3] 46/2 67/18 122/1
attenders [1] 60/3
attending [2] 116/6 133/9
attention [13] 6/8 6/8 26/8 31/6 63/12 75/9 77/2 78/22 86/25 136/25 156/13 162/6 169/3
August [7] 16/1 40/12 113/23 127/13 135/8 136/9 136/11
August 1967 [1] 40/12
August 1976 [1] 16/1
auspices [2] 79/9 88/4
Austria [1] 44/13
author [2] 109/6 148/17
authored [11] 6/22 49/15 49/19 49/20 88/3 111/9 116/1 118/9 120/25 142/23 151/4
authoring [1] 73/2
authority [7] 68/14 92/18 106/24 108/3 121/20 121/24 138/15
authors [3] 104/6 121/4 161/11
availability [4] 30/1 106/21 153/3 171/10
available [47] 7/4 7/6 11/1 13/9 17/7 17/25 18/2 20/16 22/1 22/19 24/7 30/7 33/1 34/16 40/5 41/3 43/16 44/3 44/21 55/9 57/17 63/20 65/6 72/7 89/25 94/14 98/10 98/12 104/10 104/20 105/4 105/8 105/22 105/24 110/19 131/8 131/23 132/13 134/13 135/18 138/25 154/21 156/21 156/24 159/24 166/8 170/9
average [2] 14/5 14/15
avoid [1] 23/20
awaiting [1] 56/15
award [1] 123/12
aware [12] 39/16 76/6 125/18 127/6 131/7 131/22 145/24 156/17 158/5 158/11 158/21 158/25
awareness [3] 61/9 76/10 160/1
AZT [5] 129/21 129/23 129/24 130/2 130/4

B

B1 [1] 143/24
B2 [1] 143/24
B3 [1] 143/24
baby [2] 66/21 110/12
back [24] 27/16 28/16 36/21 36/24 42/11 48/5 48/7 53/7 54/9 62/8 65/11 68/4 76/7 76/11 80/24 86/3 86/11 99/20 112/5 147/20 148/1 149/7 159/25 172/23
background [1] 154/8
bags [3] 51/20 167/5 167/6
balance [2] 17/20 168/19
ban [3] 73/19 73/23 77/6
Barré [2] 161/25 163/8
Barré-Sinoussi [2] 161/25 163/8
based [6] 8/18 11/16 35/13 47/10 48/22 60/20
basis [14] 18/21 18/24 25/1 39/19 40/6 41/23 69/24 87/9 87/21 89/16 94/4 106/2 141/18 142/19
batch [4] 11/2 11/5 79/15 107/15
batches [11] 78/7 78/10 78/11 79/10 79/20 84/10 88/16 88/19 172/3 172/6 172/6
be [270]
bear [1] 109/8
bearing [1] 45/9
bears [1] 53/2
became [10] 2/10 3/3 4/9 5/22 24/7 156/21 156/24 159/24 161/14 166/7
because [28] 9/17 15/10 22/13 24/13 25/20 27/6 32/8 32/10 33/1 35/10 35/11 38/11 48/6 57/18 112/16 116/9 117/13 119/15 119/24 127/3 127/15 129/25 130/1 140/23 141/11 145/5 147/20 160/8
become [8] 13/8 40/5 89/24 94/14 98/12 99/5 109/16 166/21
becoming [4] 9/7 21/13 82/9 131/7
been [155] 1/13 5/10 6/4 7/19 8/10 12/9 13/7 13/9 15/17 16/11 17/12 17/15 20/9 20/9 20/13 22/9 22/23 23/3 24/5 25/5 25/16 25/22 29/16 33/14 33/17 34/8 36/16 36/17 37/23 38/5 38/10 41/24 42/15 46/5 47/6 47/18 54/18 54/21 62/21 62/22 64/18 65/4 66/9 74/12 76/1 76/6 77/24 78/2 78/15 78/17 78/21 87/25 88/11 88/16 88/22 88/25 90/19 90/25 91/2 91/17 92/15 92/18 92/21 93/15 96/16 98/14 98/21 98/21 98/23 99/24 101/13 101/23 104/11 106/12 108/1 111/18 111/21 114/21 115/1 115/15 115/17 116/15 117/1 117/4 117/11 118/13 118/16 118/24 119/1 119/22 121/13 122/11 122/15 123/4 123/10 124/12 126/19 126/21 126/24 127/4 127/13 128/24 129/21 131/1 131/24 132/14 132/18 132/20 133/23 134/20 134/21 134/25 135/10 135/19 136/10 137/10 137/18 138/4 138/6 139/1 139/7 143/3 143/5 143/8 147/21 148/13 148/20 148/23 149/1 151/18 152/12 153/6 153/7 156/7 157/7 158/10 159/6 159/18 159/20 162/4 164/7 164/13 165/12 165/13 166/6 166/8 166/25 167/7 167/17 167/25 168/13 169/9 169/10 170/6 171/1
before [18] 10/18 26/17 31/14 58/3 58/10 60/7 65/1 75/16 77/4 86/6 86/9 94/13 94/23 95/21 129/10 129/24 138/9 152/25
beg [1] 160/25
began [1] 33/6
begin [3] 114/4 172/13 172/15
beginning [5] 25/9 62/13 96/23 143/14 160/21
behalf [5] 21/18 49/16 111/11 121/7 139/21
behind [2] 119/9 173/3
Behringwerke [1] 105/11
being [81] 2/7 7/6 17/14 19/19 20/11 21/2 21/16 23/18 24/25 33/4 33/11 33/24 34/6 35/3 59/18 60/19 61/5 63/21 64/13 67/8 75/7 75/12 76/13 77/2 77/18 77/22 78/6 78/8 79/8 79/8 79/11 79/19 79/20 83/15 84/15 85/13 85/16 85/18 88/3 88/7 89/3 92/1 94/9 96/1 96/15 98/22 100/4 102/25 103/19 103/23 105/14 110/12 113/24 114/2 114/25 117/20 118/2 120/8 123/10 127/6 127/22 131/15 132/7 132/9 132/22 133/5 133/17 139/4 139/20 140/12 140/21 145/7 145/25 147/20 152/6 152/9 159/9 160/22 164/8 166/1 171/15
beings [1] 88/21
belief [2] 59/18 152/11
believe [4] 35/21 40/4 92/24 165/16
belonged [1] 3/8
below [6] 23/5 46/2 81/18 112/19 123/20 163/5
benefit [1] 23/14
benefits [1] 171/9
besides [1] 157/13
best [10] 9/6 22/18 34/13 51/11 53/21 56/21 56/22 59/19 125/21 173/5
better [2] 27/7 80/18
between [41] 2/23 3/13 4/9 4/10 6/16 8/19 12/22 13/12 21/7 27/9 34/2 37/7 39/12 39/13 42/3 47/13 47/15 48/20 52/6 55/3 56/12 63/10 74/7 78/20 79/18 80/2 81/25 83/16 83/17 90/9 92/2 93/6 100/25 101/11 102/16 106/6 117/18 124/5 124/12 154/25 168/19
beyond [3] 4/16 4/16 93/2
bid [1] 139/3
Bidwell [8] 5/2 6/16 15/25 16/17 26/2 28/3 33/13 33/21
Bidwell's [2] 15/11 21/17
big [1] 32/8
bigger [1] 47/19
Biggs [36] 2/24 4/22 4/22 9/22 15/14 19/23 21/7 21/8 21/25 26/3 26/20 27/5 28/5 28/7 29/15 33/5 38/17 38/22 42/4 42/15 42/24 45/22 46/9 47/11 47/23 48/14 48/23 49/6 49/15 49/20 55/3 55/24 55/25 60/15 62/11 63/2
Biggs' [3] 11/8 55/5 60/1
bill [1] 21/14
biopsy [2] 99/7 155/25
Birmingham [1] 6/17
birth [5] 142/4 143/23 144/3 144/5 144/16
bisexual [1] 150/11
bit [3] 8/5 8/7 168/16
Blackburn [3] 42/21 42/21 43/3
Blackburn's [1] 42/25
blame [1] 23/18
blank [1] 109/20
bleed [1] 27/12
bleeding [13] 24/17 27/14 28/9 31/16 32/1 85/12 126/20 140/10 140/13 143/16 159/5 165/9 168/20
blood [80] 2/8 4/4 4/7 4/19 5/21 6/13 6/18 6/25 7/7 7/17 10/25 16/15 17/7 17/15 25/6 31/20 31/23 36/13 39/3 43/21 45/10 49/7 49/16 52/6 56/1 56/20 56/23 59/6 62/22 62/23 63/10 63/18 66/11 66/18 73/20 82/4 87/1 90/10 95/20 96/18 97/6 98/3 102/17 106/2 107/7 109/25 111/13 112/22 112/24 113/9 113/10 121/12 122/4 122/9 122/24 126/2 128/15 130/1 133/14 134/3 135/2 140/5 148/12 150/15 151/23 152/4 155/22 156/20 157/16 157/17 157/21 157/22 159/14 159/16 159/24 164/25 165/14 167/9 167/14 170/16
Bloom [36] 4/15 26/5 58/13 58/14 58/17 59/3 63/16 72/19 72/24 73/6 73/13 73/15 74/12 75/22 76/3 76/4 76/5 76/8 76/14 79/9 79/18 79/23 85/13 86/15 88/8 89/14 93/10 99/14 103/22 104/7 110/23 111/9 151/4 151/5 151/6 162/18
Bloom's [1] 73/7
Bloomberg [2] 148/10 148/17
blown [1] 68/24
BMJ [1] 113/12
board [2] 111/4 172/1
body [2] 140/8 140/15
books [1] 91/11
borne [3] 22/8 128/15 140/16
both [22] 2/12 17/9 17/11 31/8 34/6 39/8 41/16 44/16 45/22 45/23 56/7 56/17 59/5 59/14 68/7 69/18 80/19 91/20 98/19 110/12 113/7 164/23
bottom [24] 6/24 7/3 9/25 13/16 31/15 32/16 46/15 57/15 62/13 73/8 74/9 97/15 99/1 105/14 120/20 134/7 145/20 154/23 155/6 162/8 163/4 163/12 164/19 169/3
bought [3] 18/6 44/23

F:

B

bought... [1] 57/3
Boulton [1] 73/7
bound [2] 125/16 126/10
boy [1] 66/19
BPL [11] 6/12 21/8 33/21 43/23 59/11 59/13 86/20 89/5 113/21 114/7 167/15
BPLL0001351 [1] 71/24
BPLL0008096 [1] 43/2
brand [1] 105/2
brands [2] 96/8 101/20
break [9] 42/1 42/10 42/14 94/23 99/19 141/2 147/10 147/25 148/4
breaking [3] 133/22 133/23 152/6
brief [2] 142/12 154/10
briefly [4] 6/11 72/21 140/25 151/11
bright [1] 25/4
bring [1] 109/7
Bristol [3] 84/12 84/14 85/5
British [6] 30/2 30/10 42/18 44/17 44/21 110/24
Britten's [1] 28/20
broader [2] 38/3 122/1
broadly [4] 1/6 10/5 38/16 122/19
brought [1] 77/2
BTS [3] 122/8 122/13 133/6
Buckinghamshire [1] 139/22
budget [2] 22/9 107/23
budgetary [1] 16/5
buildings [2] 40/23 41/9
built [1] 4/18
burden [1] 9/8
but [128] 1/21 2/4 2/21 2/22 4/21 5/16 6/6 9/10 9/22 10/17 14/24 15/25 16/9 18/22 18/24 23/3 23/4 23/10 23/14 23/20 24/24 25/18 26/14 27/18 28/13 29/3 29/5 32/11 32/15 35/2 36/2 36/20 38/2 38/9 38/12 40/1 41/3 42/5 44/1 44/16 46/12 47/14 49/1 49/24 51/1 53/5 54/9 54/23 57/22 58/20 59/8 59/12 60/17 63/11 64/6 67/23 68/4 69/2 69/22 71/12 72/21 73/7 73/14 73/18 74/9 76/24 77/23 78/20 79/17 79/22 80/5 85/16 86/6 86/9 87/17 87/25 88/2 89/1 91/6 91/7 91/21 91/23 92/18 93/7 93/11 108/7 109/3 109/16 109/21 110/5 110/20 112/13 114/7 114/15 114/16 116/10 116/13 117/19 122/3 122/13 122/17 124/4 125/9 126/13 128/21 130/4 132/13 133/7 133/11 134/16 142/18 144/22 146/20 151/16 151/18 152/21 153/24 154/8 155/2 158/9 158/24 161/11 163/6 165/4 166/10 168/7 169/9 173/1
buy [7] 20/5 28/1 34/14 40/9 40/14 57/18 109/9
buying [1] 58/7
by [196]
by Behringwerke [1] 105/11

C

C1 [1] 144/3
C2 [1] 144/4
CABO0000195 [1] 149/13
calculation [1] 14/24
calendar [1] 142/17
California [1] 66/20
call [3] 41/14 57/15 64/16
called [3] 3/18 6/23 148/11
calling [1] 79/5
came [6] 6/19 37/25 58/13 91/7 131/20 158/13
can [143] 7/2 7/11 7/14 7/15 7/17 9/24 10/2 11/21 11/23 14/19 18/11 19/4 19/15 19/15 19/22 20/13 20/22 21/17 22/14 23/5 26/2 31/5 32/4 33/10 34/2 35/21 36/3 36/13 38/18 40/11 42/22 42/25 44/9 45/1 45/19 46/8 46/11 47/20 48/2 49/1 49/13 51/7 54/23 55/4 55/11 56/3 60/14 60/18 62/8 62/11 62/13 64/6 65/18 66/3 66/22 70/22 71/15 71/16 71/17 72/1 73/8 74/9 75/6 76/18 76/24 78/12 80/5 81/3 82/14 82/16 83/9 83/13 83/15 83/21 84/3 84/6 87/13 90/8 92/11 93/2 93/9 94/2 94/13 94/20 94/25 95/12 99/19 100/14 103/25 105/14 106/22 107/18 108/3 108/20 109/2 109/9 110/17 110/20 111/2 111/9 112/25 113/18 113/21 115/14 115/21 116/13 120/1 120/23 121/9 122/5 122/23 125/19 127/23 128/22 132/9 133/4 134/8 135/5 135/9 135/20 136/24 137/1 137/12 137/21 140/18 142/1 143/13 145/15 146/11 147/3 147/7 148/9 149/18 149/20 149/23 149/25 150/5 154/24 157/12 158/18 160/1 164/2 170/2
can't [1] 117/17
Cancer [2] 121/1 121/1
candidate [1] 127/25
cannot [8] 10/18 23/20 40/21 44/21 57/8 108/23 138/23 158/8
capable [1] 125/8
capacity [2] 19/24 43/7
Cardiff [6] 73/6 79/3 79/4 79/13 79/16 151/3
cards [4] 148/21 148/22 148/25 149/1
care [11] 8/18 9/4 19/16 96/14 107/7 125/25 127/7 130/9 154/1 171/19 172/25
carefully [2] 27/17 105/24
carried [11] 78/4 89/3 95/12 99/8 101/5 123/23 127/11 146/10 146/15 148/10 157/1
carrier [1] 46/22
carriers [2] 90/24 99/5
carry [4] 69/10 92/17 105/18 159/22
carrying [2] 92/14 159/21
cars [1] 140/19
case [29] 17/11 26/13 50/19 66/19 66/21 69/16 74/25 75/20 76/1 76/6 78/5 78/25 79/3 79/6 79/7 79/14 79/16 84/23 85/5 87/9 119/11 120/15 126/3 126/4 126/14 127/2 136/18 157/3 170/1
cases [27] 20/18 39/13 64/18 64/21 66/3 66/17 67/3 67/16 67/23 74/22 76/17 76/21 76/24 85/7 85/8 110/10 124/22 124/22 125/2 125/3 125/13 125/19 129/20 134/12 143/25 144/7 152/24
cash [6] 22/7 102/16 103/11 128/23 128/23 132/16
Catalan [1] 123/14
categories [2] 143/19 144/1
catered [1] 94/2
caught [3] 48/7 124/20 153/7
causative [1] 111/20
cause [9] 124/25 125/19 143/24 159/9 160/23 161/10 161/23 162/7 163/9
caused [3] 64/22 108/2 162/13
causes [1] 66/5
causing [1] 54/22
cautious [1] 161/12
CBLA0000135 [1] 44/25
CBLA0000206 [1] 55/2
CBLA0001831 [1] 103/25
CBLA0003258 [1] 86/12
CDC [2] 66/2 66/13
cells [1] 13/1
cent [26] 12/11 12/13 13/3 15/2 15/2 15/4 15/4 15/7 15/8 15/14 15/16 15/18 33/7 48/16 48/19 48/21 96/2 100/25 104/14 114/4 116/8 120/12 129/4 129/5 129/6 131/4
central [6] 4/3 8/4 21/3 45/25 47/24 149/10
centralised [1] 87/17
centrally [4] 20/5 20/22 21/3 59/5
centre [129] 1/5 1/10 2/6 2/6 2/7 2/10 2/11 2/19 3/3 4/18 4/22 4/25 5/10 5/16 5/20 5/25 12/4 12/12 14/3 15/9 15/15 16/4 16/16 18/7 19/20 19/25 22/19 24/1 24/3 24/20 25/7 25/8 25/25 26/25 31/23 31/24 38/20 38/23 41/18 42/19 43/7 43/25 45/24 52/5 52/7 58/22 60/4 60/4 63/12 63/24 67/2 69/8 71/19 72/6 73/1 73/22 77/9 78/17 78/22 84/1 85/15 86/15 88/4 88/7 91/5 93/13 94/4 94/15 96/13 101/6 104/1 104/3 107/5 107/16 114/22 117/2 118/14 121/3 123/18 124/2 129/8 129/16 130/2 133/14 134/6 134/23 137/23 138/8 138/14 138/16 139/22 139/24 141/17 142/2 142/5 142/25 143/6 144/2 146/1 146/6 146/7 146/15 146/16 146/18 146/19 148/14 148/16 148/22 150/3 151/14 152/2 154/6 156/12 156/16 158/5 158/7 160/4 162/18 164/1 164/7 167/1 170/9 170/18 170/21 170/24 171/5 171/8 171/20 171/21
centre's [1] 170/14
centres [71] 5/9 6/14 7/18 9/3 9/6 9/20 10/4 10/5 10/15 12/6 12/10 13/13 20/4 20/6 20/10 24/22 26/10 26/12 26/15 32/11 43/21 44/4 44/6 47/4 47/8 50/14 50/21 51/8 58/4 59/7 78/2 78/14 79/21 84/19 84/22 86/3 94/6 101/17 106/1 110/25 111/12 112/9 112/11 112/15 115/24 116/7 116/8 116/8 116/23 117/12 117/12 117/14 117/23 118/1 118/12 119/23 119/24 120/3 121/8 133/1 138/1 141/18 142/9 142/11 152/21 154/3 159/16 167/1 167/7 167/10 167/15
certain [4] 109/2 110/13 155/22 158/8
certainly [16] 36/20 69/17 76/13 76/25 79/5 79/12 91/15 110/19 110/20 125/9 126/14 135/8 138/5 145/4 159/4 161/16
certainty [1] 126/8
certificate [2] 90/1 124/19
certificates [1] 124/10
cessation [1] 165/14
cetera [9] 35/24 98/3 98/3 105/1 140/12 144/3 144/3 144/8 153/20
chair [6] 3/13 4/9 4/9 30/15 42/20 72/24
chaired [1] 3/20
Chairman [1] 43/7
chance [2] 52/17 52/19
change [14] 67/24 69/1 73/23 76/15 85/17 114/1 114/10 114/14 115/12 116/16 144/12 144/13 163/18 163/20
changed [4] 37/4 37/13 109/23 159/3
changes [1] 160/11
changing [2] 72/8 160/13
Chappell [1] 64/11
Chappell's [1] 68/15
characteristics [1] 89/10
Charles [3] 4/23 31/8 102/19
cheaper [1] 57/13
check [2] 18/22 76/24
chief [3] 5/12 43/4 44/24
children [9] 2/12 8/2 37/12 38/7 69/21 72/14 97/20 162/24 168/11
chimpanzee [1] 102/3
chimpanzees [4] 88/17 92/17 92/25 102/5
Chiron [1] 128/1
choice [6] 27/22

F:

C

choice... [5] 35/24 36/1 36/6 36/11 54/1
Christine [1] 172/17
Christmas [7] 3/16 39/3 120/15 137/9 137/11 137/20 169/10
chronic [11] 5/18 56/25 64/6 99/7 100/11 100/23 101/21 132/3 134/8 156/3 157/4
chronically [1] 16/23
Churchill [2] 4/20 108/5
circular [1] 85/14
circulated [2] 27/4 112/9
circulating [1] 22/17
circumspect [1] 72/16
circumstances [1] 158/8
cities [1] 62/20
citizens [1] 56/21
claim [1] 92/21
claimed [1] 57/7
claims [1] 92/19
clarified [1] 108/1
class [1] 93/16
clear [25] 4/4 11/16 26/13 33/19 59/25 65/3 67/17 69/15 69/23 74/6 76/5 80/8 84/23 88/23 109/15 127/15 128/21 132/14 135/17 136/9 140/20 142/18 155/8 157/13 157/20
clear-cut [1] 88/23
clearing [1] 112/14
clearly [16] 18/24 22/12 25/17 29/5 56/22 62/4 73/21 78/21 83/16 109/21 110/5 146/1 155/1 161/9 168/7 169/24
clinic [1] 99/6
clinical [26] 3/25 5/11 23/9 28/10 87/9 89/24 90/1 91/14 92/1 92/15 96/9 97/25 104/10 115/10 121/2 121/24 128/13 136/20 144/6 144/19 155/15 158/24 160/8 160/11 160/14 169/19
clinically [4] 17/12 35/18 99/8 155/20
clinicians [7] 9/13 31/22 152/1 158/3 161/1 170/11 171/8
clinics [1] 57/1
close [3] 8/19 12/21 79/17
closely [3] 73/12 78/7 79/8
closer [1] 111/7
clotting [1] 56/1
CMO [1] 38/24
co [13] 9/17 12/22 49/20 51/21 73/2 77/18 79/24 88/3 94/16 105/23 116/9 143/5 150/17
co-authored [2] 49/20 88/3
co-authoring [1] 73/2
co-location [1] 9/17
co-operate [1] 116/9
co-operation [1] 12/22
co-ordinate [2] 94/16 150/17
co-ordinated [3] 77/18 105/23 143/5
co-ordinating [1] 79/24
coagulation [3] 4/19 66/7 100/21
code [1] 144/16
codes [1] 147/10
cohort [1] 81/11
cohorts [2] 81/14 91/22
COLL0000001 [1] 36/14
collaborate [1] 67/3
collaboration [2] 8/19 106/6
collaborative [1] 94/3
colleague [1] 57/25
colleagues [5] 7/16 23/20 63/9 74/11 109/8
collect [1] 91/5
collected [4] 11/3 62/18 62/23 142/8
collecting [3] 5/5 115/23 143/3
collection [2] 98/18 143/5
collective [1] 77/8
collects [1] 143/21
College [1] 27/1
column [1] 56/3
Colvin [4] 48/20 53/19 123/6 142/14
combinations [1] 165/4
come [20] 16/24 18/9 26/17 27/16 28/16 42/1 42/11 49/5 61/1 61/13 63/11 65/11 66/16 73/1 86/3 91/4 93/4 94/1 141/14 149/7
comes [3] 35/23 35/25 40/9
coming [2] 2/13 172/23
comment [16] 53/2 53/2 83/14 156/14 156/15 157/25 158/19 161/9 161/11 161/20 162/11 163/5 163/17 164/4 164/17 169/13
comments [2] 161/19 163/10
commercial [82] 10/12 10/25 11/10 13/2 15/6 15/9 15/16 17/6 18/12 18/14 19/2 20/2 20/8 21/5 21/21 22/1 24/6 25/13 25/17 28/14 30/1 30/13 33/24 34/14 36/8 37/14 37/22 37/24 37/24 38/8 40/6 40/13 41/4 41/19 44/11 44/14 44/22 48/1 55/6 55/8 55/12 56/9 56/14 57/4 58/7 59/1 59/11 59/14 59/22 62/16 62/21 63/1 63/5 69/19 70/12 70/21 80/17 81/1 81/2 81/10 81/14 82/24 83/20 84/11 84/16 84/19 87/2 88/9 93/23 94/18 95/22 98/20 101/22 103/24 112/17 114/12 114/16 115/6 115/13 115/16 156/23 168/23
commercially [6] 17/25 18/1 30/7 34/17 57/3 108/14
committee [20] 3/23 4/1 4/3 4/7 4/11 30/18 43/13 47/11 49/8 49/17 74/13 75/10 77/5 141/8 149/18 149/21 149/22 149/25 150/6 150/19
committees [4] 3/9 49/9 149/11 153/19
common [2] 32/1 152/21
commoner [1] 166/14
commonest [2] 159/9 160/23
communicated [2] 132/19 153/1
communication [5] 50/1 79/18 124/5 152/16 152/20
communications [3] 55/3 82/25 103/8
companies [4] 11/1 56/9 88/9 90/19
company [1] 56/10
comparative [3] 46/25 62/14 169/21
compare [1] 101/18
compared [3] 9/20 25/10 123/18
comparison [5] 46/13 47/13 51/3 53/3 117/18
comparisons [2] 53/12 154/24
complacent [1] 73/17
complaint [2] 19/6 138/6
completed [1] 104/11
completely [4] 92/10 137/4 167/13 168/6
completes [1] 172/7
completion [1] 128/14
complex [1] 121/6
complication [1] 111/16
complications [2] 52/11 60/16
components [1] 12/25
comprehensive [1] 139/11
comprehensively [1] 2/2
comprised [1] 78/20
compromised [1] 80/10
computer [9] 119/20 143/10 146/14 146/15 146/15 146/19 146/20 147/1 147/7
concentrate [110] 3/15 6/20 7/9 7/10 10/12 10/12 10/14 10/22 11/1 11/7 11/10 11/11 12/20 12/21 15/3 15/15 15/16 17/14 18/2 18/5 20/3 20/5 27/23 28/23 29/6 29/18 32/25 34/5 34/14 37/2 37/3 37/4 37/5 37/10 37/22 37/24 37/25 38/6 38/11 40/15 43/19 44/14 44/17 44/19 44/20 46/4 46/6 46/14 46/17 46/18 47/9 47/15 47/25 48/2 50/8 50/18 50/22 51/3 51/17 51/18 52/13 53/13 53/25 59/22 66/25 67/12 71/2 71/8 71/10 72/8 80/17 80/21 81/2 81/23 82/24 83/11 83/19 83/20 84/20 90/18 93/19 95/2 95/11 96/4 100/12 100/19 100/25 101/7 101/14 101/19 102/5 104/16 111/22 112/3 112/13 112/15 128/10 154/12 154/15 154/19 154/25 156/24 159/17 162/21 164/21 164/24 166/7 166/15 168/3 168/18
concentrated [1] 7/24
concentrates [57] 9/19 12/2 13/14 14/19 16/16 18/12 18/14 19/2 21/5 28/15 33/24 34/16 38/8 39/7 39/20 40/13 44/15 47/14 49/18 52/9 54/4 58/3 58/23 59/19 59/22 64/24 69/10 69/14 69/19 70/1 70/3 70/4 70/12 70/13 70/14 70/20 70/22 72/13 75/11 84/19 86/17 86/21 88/22 88/24 89/1 89/5 90/5 95/21 96/17 107/10 111/25 113/5 152/5 167/17 168/23 169/14 171/10
concept [2] 23/9 123/2
concern [12] 28/12 58/20 84/18 85/4 108/2 110/24 111/13 117/13 119/25 131/15 140/3 147/23
concerned [14] 8/23 26/1 30/6 36/21 41/17 45/7 63/8 78/2 82/24 92/16 94/10 140/21 144/4 160/10
concerning [7] 36/22 61/20 68/19 142/25 150/9 158/22 161/25
concerns [1] 130/20
concluded [1] 26/23
concludes [3] 109/11 170/4 172/10
concluding [1] 156/11
conclusion [6] 8/13 8/16 27/22 29/21 41/24 163/11
conclusions [1] 53/11
Concord [1] 130/5
condition [2] 68/24 156/25
conditions [1] 3/15
conduct [1] 27/15
conducted [1] 4/19
confidence [2] 119/19 146/24
confident [1] 108/20
confidential [7] 144/23 145/1 145/5 145/7 145/9 145/13 145/13
confidentiality [5] 116/10 117/14 117/24 119/25 142/25
confirm [4] 80/20 81/23 126/8 128/12
confirmation [2] 122/15 123/3
confirmed [3] 26/10 133/17 142/20
confirming [1] 86/19
confirms [1] 124/15
confusion [1] 161/24
congress [1] 77/15
conjunction [1] 62/2
connection [1] 63/22
cons [1] 57/11
conscious [1] 24/5
consent [15] 97/18 97/22 122/8 122/15 122/18 122/20 123/4 123/9 141/9 147/17 149/3 152/9 152/14 171/16 171/24
consequence [4] 25/11 99/10 131/24 170/23
consequences [3] 45/8 57/14 125/21
consequent [1] 58/24
conservation [1] 53/14
conservative [1] 20/24
consider [16] 6/2 30/18 43/13 50/21 113/4 118/4 120/10 138/10 146/2 151/11 155/1 156/5 160/17 165/2 170/8 170/13
considerable [4] 25/17 59/15 108/2 135/15
consideration [6] 30/19 47/24 56/16 61/5 147/15 164/12
considered [3] 56/5 122/11 123/10
considering [7] 13/24 55/21 83/15 84/25 86/10 86/16 156/7
considers [1] 124/9
consistent [1] 156/2
consternation [1] 110/14

C

constitute [1] 89/13
constituted [2] 12/13 13/3
construction [1] 67/22
consultant [2] 19/8 64/11
contact [5] 140/7 140/8 140/15 144/7 145/17
contacts [1] 145/18
contain [2] 54/5 143/20
containers [1] 56/19
containing [4] 35/24 36/1 50/3 52/17
contains [2] 11/5 146/12
contaminated [1] 125/14
contamination [2] 126/15 127/18
contemplated [2] 99/9 103/20
contemporaneous [1] 61/4
content [1] 166/14
continue [11] 18/3 58/7 72/16 108/23 115/19 139/15 159/6 162/20 164/18 168/17 168/23
continued [2] 37/5 56/7
continues [2] 27/19 96/5
continuing [2] 83/23 162/7
contract [1] 41/1
contracted [3] 95/21 101/8 126/1
contracting [2] 52/20 168/21
contracting AIDS [1] 168/21
contrary [2] 122/20 126/10
contrast [1] 12/12
contributed [2] 117/15 117/16
contributing [1] 54/3
contribution [3] 32/22 81/8 82/12
contributory [1] 124/4
control [3] 23/7 88/19 104/18
controlled [3] 87/18 89/17 93/1
controls [1] 67/14
Convenience [2] 51/14 51/14
convenient [3] 42/9 99/19 147/24
conversation [2] 80/12 140/2
converted [1] 114/24
convincingly [1] 163/8
cope [2] 81/3 109/2
copied [3] 73/8 138/15 162/4
copy [3] 21/9 73/14 138/19
Core [5] 1/25 148/24 170/6 171/25 173/3
coroner [9] 124/4 124/6 124/9 124/13 124/13 125/6 125/22 126/25 127/9
coroner's [3] 124/15 125/5 126/18
coronial [2] 124/10 126/22
corporate [1] 35/6
correct [1] 42/6
correctly [1] 41/16
correspondence [14] 6/15 19/3 21/7 22/17 38/2 76/12 80/1 80/6 80/24 90/9 92/2 102/14 102/16 105/6
cost [8] 18/6 22/21 24/6 40/10 41/5 44/17 57/6 107/17
costly [2] 40/25 41/6
costs [2] 53/6 109/4
could [38] 6/21 8/7 9/21 26/25 28/3 28/8 29/9 31/24 32/3 34/10 36/14 40/19 48/5 48/11 55/13 55/15 71/10 74/18 75/1 87/5 90/12 91/22 92/22 98/6 98/14 98/16 102/15 109/3 109/12 112/5 116/9 119/7 121/21 123/2 126/6 137/18 148/7 167/10
council [3] 149/20 150/24 151/7
Council's [3] 3/12 3/14 49/7
counselling [1] 130/16
counter [1] 73/19
counter-productive [1] 73/19
countries [4] 17/13 62/21 74/22 108/16
country [20] 2/12 2/15 20/4 21/23 29/20 34/17 40/17 40/22 50/5 55/11 56/11 57/4 64/17 69/9 70/6 70/19 78/23 133/2 138/2 157/2
couple [4] 9/24 32/15 86/11 138/11
couples [1] 131/6
course [31] 1/25 6/9 16/5 23/1 24/5 54/24 60/11 61/6 62/5 72/18 72/23 73/10 73/23 90/4 91/16 107/14 123/7 125/18 127/20 132/21 142/17 149/6 153/21 155/2 155/8 156/8 160/5 160/8 164/12 167/8 173/1
cover [2] 18/10 95/18
covers [1] 82/8
Cowdell [1] 24/4
Craske [34] 60/6 63/16 63/18 64/4 65/25 66/3 67/1 67/7 67/15 74/1 74/7 74/10 75/7 75/13 75/18 75/25 76/4 76/4 77/18 84/7 85/9 85/10 93/10 93/22 94/21 98/23 99/14 101/15 103/21 104/7 146/24 158/9 158/14 164/4
Craske's [1] 65/18
created [1] 68/20
cripple [1] 9/8
crippling [2] 39/14 165/10
crisis [1] 86/14
criteria [2] 96/14 97/4
critical [1] 2/25
crop [1] 5/1
Cross [1] 41/2
CRR [3] 156/14 157/25 158/19
CRR Comment [1] 157/25
cryo [2] 72/16 165/24
cryoprecipitate [94] 3/12 7/8 7/14 7/17 7/23 9/19 10/11 10/13 10/15 11/9 12/7 12/10 12/12 12/14 12/16 13/1 13/13 13/19 13/24 14/19 15/1 15/19 16/14 26/9 26/11 28/24 29/2 29/4 29/19 30/21 32/5 32/18 34/6 43/18 43/20 44/3 46/13 47/14 47/15 48/9 49/18 50/9 50/12 51/4 51/6 51/10 51/16 51/20 52/1 52/3 52/22 53/12 53/21 53/21 54/21 67/14 71/2 71/12 84/14 84/17 97/8 100/13 100/22 112/11 112/23 113/5 154/11 154/14 154/16 154/25 159/3 159/7 159/13 159/15 159/21 160/20 162/23 162/24 163/15 164/22 164/24 165/1 166/5 166/9 166/10 166/20 166/24 167/4 167/5 167/10 167/14 168/2 168/6 168/11
cupboard [2] 146/21 147/1
cupboards [1] 146/12
current [5] 57/8 84/6 107/6 128/9 139/1
currently [3] 69/15 98/25 104/19
cut [3] 19/15 22/9 88/23
Cutter [1] 104/21

D

daily [2] 22/8 82/13
Daily Mail [1] 82/13
damage [2] 134/8 157/1
danger [2] 93/3 94/4
dangerous [1] 17/22
dangers [3] 162/21 168/19 168/20
data [27] 5/6 50/23 60/21 82/11 86/4 115/23 115/24 117/15 119/19 129/8 129/8 136/21 141/15 141/17 143/1 143/7 145/25 146/5 146/13 146/14 146/16 146/17 147/15 147/18 148/15 148/22 154/21
Database [1] 147/19
date [27] 49/24 78/4 114/24 114/25 117/5 117/11 118/10 118/17 119/2 119/3 119/4 119/22 120/21 127/14 128/20 130/5 132/6 142/4 143/23 143/23 144/2 144/5 144/13 144/16 164/9 169/8 172/15
dated [22] 16/8 22/15 45/2 58/18 85/25 87/25 87/25 100/7 108/4 113/15 116/2 116/19 120/23 124/8 129/12 131/17 133/13 136/8 137/7 138/13 141/24 169/6
dates [3] 18/18 82/5 152/23
David [1] 41/20
day [2] 131/21 167/6
days [5] 1/16 31/17 41/21 107/1 132/16
DDAVP [1] 162/23
deal [11] 2/4 5/6 22/16 24/23 40/2 68/20 140/25 143/17 151/15 153/12 169/17
dealing [5] 1/20 31/16 133/19 140/10 158/3
deals [5] 53/5 53/6 53/7 53/8 59/11
Dear [5] 24/4 90/14 102/19 107/3 109/20
death [15] 39/12 85/6 124/10 124/18 124/25 125/7 126/19 129/24 143/24 143/24 144/13 155/16 159/9 160/23 165/10
deaths [1] 120/21
debate [1] 147/16
deceased [1] 124/24
December [14] 36/20 43/3 59/9 85/22 85/25 86/20 106/16 107/2 108/4 110/10 162/9 169/1 169/2 169/7
December 1983 [1] 162/9
December 1984 [4] 36/20 85/22 106/16 169/1
decided [2] 27/24 77/5
decision [11] 42/20 67/20 69/1 79/24 96/11 106/17 115/8 164/17 168/10 168/17 168/23
decision-making [1] 79/24
decisions [1] 171/4
declining [2] 77/14 117/23
dedicated [2] 146/11 146/21
defects [2] 66/7 100/21
defendants [2] 6/10 155/9
deficiency [3] 21/20 64/9 65/24
define [1] 82/22
definite [1] 132/8
definition [2] 98/4 125/8
degree [5] 45/16 67/23 70/4 81/21 82/23
delay [4] 31/25 152/19 152/24 152/25
delayed [2] 167/18 169/9
delays [1] 132/22
delivered [1] 134/5
demand [4] 13/22 27/9 27/10 29/14
demonstrated [1] 76/10
Denmark [2] 77/13 77/15
denote [2] 117/3 118/15
dental [5] 24/18 138/19 138/22 139/6 139/16
department [22] 9/2 19/7 19/23 20/1 21/3 28/1 30/16 42/5 42/22 43/12 45/1 55/4 55/19 84/24 109/9 113/16 129/14 133/5 137/22 138/19 138/22 139/6
Department ... I have [1] 138/19
depend [1] 115/9
dependent [2] 29/19 166/1
deplete [1] 29/11
deploring [1] 87/20
derived [9] 10/24 11/2 11/4 17/6 17/14 52/14 52/16 105/16 111/25
describe [1] 161/9
described [7] 8/9 29/15 31/2 88/13 95/25 152/5 153/5
describes [8] 31/21 32/13 99/11 141/23 143/13 153/25 163/15 165/11
describing [3] 7/5 26/20 35/3
description [7] 7/12 7/13 11/16 97/24 142/1 153/4 164/13
deserve [1] 41/22
Desforges [1] 159/15
Desforges' [1] 158/16
designated [2] 9/3 154/5
designation [1] 154/3
designing [1] 62/1
desirability [1] 29/25
desirable [1] 56/17
despite [2] 16/22 21/17
destroy [1] 137/17

F:

D

destroyed [4] 137/10 137/20 137/24 138/5
detail [9] 27/17 28/17 62/7 78/18 116/13 129/3 141/11 151/15 153/24
detailed [7] 5/14 97/25 134/18 144/9 144/18 155/17 164/17
details [8] 74/24 75/20 82/2 82/8 102/10 105/12 117/22 144/6
detect [1] 68/23
determine [1] 89/4
determined [2] 20/18 98/5
determining [1] 102/1
develop [4] 97/14 132/3 157/4 170/17
developed [7] 5/22 127/22 127/25 129/19 154/3 159/2 160/15
developing [10] 63/7 68/24 83/23 86/7 86/13 96/3 122/21 157/15 157/21 170/22
development [8] 3/1 4/4 46/3 56/10 95/4 101/22 157/11 167/16
developments [3] 55/1 65/25 75/13
DHSC0100005 [1] 21/6
DHSC0100025 [1] 38/19
DHSS [5] 3/17 19/13 20/5 47/23 68/21
diagnosed [2] 130/3 171/20
diagnosing [2] 78/3 78/15
diagnosis [8] 119/10 143/23 144/13 152/16 152/16 152/19 152/20 153/1
Diagnosis/Registration [1] 119/10
did [15] 6/12 32/8 117/15 117/16 124/14 127/7 127/17 135/17 159/22 170/16 170/18 170/21 170/24 171/3 171/21
didn't [4] 15/9 52/24 76/18 144/22
died [9] 66/9 84/11 84/13 111/19 124/2 127/8 129/20 129/23 143/22
dies [1] 125/15
difference [7] 13/12 32/8 35/19 39/12 39/13 54/18 169/20
differences [2] 27/9 81/24
different [11] 3/9 49/2 49/3 50/19 90/21 101/20 104/9 137/5 143/18 143/19 171/5
difficult [12] 21/21 26/23 49/10 71/12 93/1 104/17 125/11 128/18 131/6 154/24 166/12 167/7
difficulties [4] 16/12 53/23 108/8 153/8
difficulty [2] 91/2 166/9
dilemma [2] 115/18 122/13
diminishing [1] 17/16
dire [1] 57/19
direction [1] 73/11
director [15] 1/9 4/23 19/25 28/6 31/20 33/17 63/13 96/13 117/3 118/15 147/13 169/11 170/19 170/22 170/25
director's [1] 115/10
directors [62] 25/25 27/14 29/9 30/12 30/20 38/20 41/18 42/19 43/8 43/25 44/4 44/5 44/18 50/20 58/22 60/4 60/5 63/24 67/3 67/8 71/20 72/1 72/6 73/22 77/9 85/15 85/18 86/16 87/21 88/7 93/13 93/22 94/16 99/14 103/23 104/3 105/25 106/6 106/17 107/5 111/11 112/8 117/6 117/21 118/21 119/7 119/13 121/7 142/3 143/1 143/3 143/14 145/22 146/1 156/12 158/5 160/4 162/18 164/1 164/7 168/13 171/5
Directors' [3] 84/2 156/17 158/7
directorship [1] 1/11
disadvantage [1] 46/16
disadvantages [3] 50/2 160/21 171/9
disagree [1] 22/6
disc [1] 146/16
discontinued [2] 75/3 139/8
discouraged [1] 84/21
discuss [2] 86/20 107/6
discussed [9] 30/4 30/6 64/10 64/20 81/19 109/23 158/24 160/3 168/6
discusses [2] 31/19 143/10
discussing [3] 33/14 79/24 89/23
discussion [29] 26/7 26/17 26/18 27/19 28/2 28/19 29/14 31/10 32/19 42/16 46/10 54/7 67/6 67/9 67/20 74/4 74/7 84/9 84/24 85/4 85/6 87/4 87/6 121/17 122/6 122/17 124/12 139/13 161/3
discussions [2] 51/23 60/8
disease [16] 3/16 5/18 8/24 39/3 99/7 120/16 129/2 129/7 132/3 134/13 137/9 137/11 137/20 144/11 156/3 157/5
disorder [3] 82/3 111/18 126/21
disorders [3] 6/25 85/12 143/16
dispel [1] 65/3
display [1] 110/20
disseminated [1] 147/3
dissemination [1] 86/2
distinction [1] 52/5
distinguish [1] 49/10
distress [1] 125/19
distributed [1] 35/4
distribution [1] 81/24
district [6] 106/23 107/22 108/5 109/6 138/25 139/2
districts [1] 62/19
disturbing [1] 112/20
disturbs [1] 114/13
diverted [1] 159/18
do [40] 5/13 20/22 22/2 23/4 23/10 24/14 24/20 39/17 41/6 49/5 49/24 61/8 61/11 63/24 70/16 71/14 72/17 72/25 73/17 75/21 80/13 83/11 91/13 92/19 93/2 110/22 117/15 117/24 124/24 125/20 126/13 130/20 136/17 137/16 138/24 143/20 149/14 161/2 167/7 172/14
doctor [1] 34/12
doctor's [1] 124/19
doctors [2] 55/9 134/19
document [31] 4/12 9/12 15/20 26/13 30/25 31/2 33/5 69/20 85/21 85/25 86/2 86/18 90/3 96/1 100/2 100/7 100/8 111/6 116/1 119/12 133/12 133/12 134/22 136/25 141/22 142/22 142/23 145/1 169/6 169/9 169/10
document's [1] 162/4
documentary [1] 126/7
documentation [9] 1/20 2/2 16/3 18/23 19/18 60/23 61/4 110/18 148/23
documents [17] 5/1 6/1 33/23 42/2 45/13 57/22 59/17 60/10 61/7 61/21 63/8 68/8 69/16 80/25 86/9 138/11 151/2
does [14] 20/25 48/16 54/4 54/9 54/11 71/1 75/21 75/24 109/16 125/2 131/25 134/16 137/14 140/14
doesn't [6] 24/23 53/6 54/17 76/19 135/3 167/25
doing [2] 88/23 135/11
don't [22] 1/15 18/23 45/13 46/11 48/24 48/24 49/24 54/9 58/19 63/8 68/25 79/21 93/7 98/25 109/18 110/5 110/19 132/13 133/11 134/4 149/4 168/4
donated [1] 56/20
donation [1] 52/18
donations [6] 10/25 46/19 47/2 54/3 101/12 113/11
done [16] 18/24 23/3 27/1 31/11 32/13 37/23 40/14 41/25 58/9 70/22 83/15 133/23 141/7 142/2 164/13 171/1
donor [14] 11/5 29/25 38/14 53/15 78/10 97/8 104/25 122/24 123/3 133/22 133/24 154/17 154/19 166/20
donors [29] 11/3 11/6 16/20 29/23 39/21 40/8 46/21 52/14 52/16 62/19 62/23 63/6 84/13 112/23 113/22 113/25 114/7 114/10 114/22 115/20 122/17 133/16 133/16 133/20 134/3 134/20 135/2 154/17 159/24
donors/patients [1] 133/16
Dormandy [4] 28/23 29/1 32/17 32/17
dosage [1] 24/13
dose [2] 24/16 65/1
doses [2] 113/2 166/24
doubt [15] 6/2 9/17 13/9 68/19 73/11 89/12 105/5 112/21 120/9 157/6 160/16 165/2 170/2 172/25 173/4
down [24] 13/6 22/25 24/10 27/21 30/5 49/25 50/6 51/5 52/12 52/23 65/23 73/15 89/20 97/10 104/6 111/7 139/4 147/11 149/24 150/4 159/20 161/6 168/15 169/15
downstairs [1] 173/4
Dr [370]
Dr Bidwell [6] 6/16 15/25 16/17 26/2 33/13 33/21
Dr Bidwell's [1] 15/11
Dr Biggs [33] 2/24 4/22 15/14 19/23 21/7 21/8 21/25 26/3 26/20 27/5 28/5 28/7 29/15 33/5 38/17 38/22 42/4 42/15 42/24 46/9 47/11 47/23 48/14 48/23 49/6 49/15 49/20 55/3 55/24 55/25 60/15 62/11 63/2
Dr Biggs' [3] 11/8 55/5 60/1
Dr Blackburn [1] 42/21
Dr Bloom [3] 26/5 88/8 110/23
Dr Boulton [1] 73/7
Dr Britten's [1] 28/20
Dr Cash [4] 102/16 103/11 128/23 132/16
Dr Catalan [1] 123/14
Dr Charles Rizza [2] 4/23 31/8
Dr Colvin [4] 48/20 53/19 123/6 142/14
Dr Cowdell [1] 24/4
Dr Craske [26] 60/6 63/16 63/18 64/4 66/3 67/1 67/7 67/15 74/1 74/7 74/10 75/7 75/13 76/4 76/4 84/7 85/9 85/10 93/10 93/22 94/21 98/23 101/15 103/21 158/14 164/4
Dr Craske's [1] 65/18
Dr David [1] 41/20
Dr Desforges [1] 159/15
Dr Dormandy [3] 28/23 29/1 32/17
Dr Ethel Bidwell [1] 5/2
Dr Forbes [1] 110/23
Dr Galbraith [3] 77/23 85/7 150/2
Dr Galbraith's [1] 85/4
Dr Godber [1] 38/23
Dr Grant [1] 16/15
Dr Gunson [1] 150/2
Dr J [1] 158/9
Dr James [4] 5/9 5/12 31/7 31/12
Dr Jane Desforges' [1] 158/16
Dr Jean [1] 31/20
Dr Joan Trowell [1] 5/15
Dr John Craske [1] 146/24
Dr Johnson [1] 139/6
Dr Johnson's [1] 138/21
Dr Judith Pool [1] 7/15
Dr Lane [4] 86/18 87/6 87/11 87/19
Dr Lane's [2] 86/22 87/15
Dr Lawrence [1] 66/2
Dr Lee [4] 80/11 81/6 81/15 81/16
Dr Macfarlane [2] 4/21 8/11
Dr Matthews [5] 5/20 26/3 28/22 32/7 84/4
Dr Matthews' [1] 32/22
Dr Maycock [5] 21/8 21/9 22/3 26/11 46/10
Dr Maycock's [2] 20/7 45/6

F:

D

Dr Mortimer [1] 128/2
Dr Rizza [168] 1/14 2/25 3/8 5/20 6/3 6/23 7/4 16/8 19/10 22/15 25/18 26/3 32/16 33/13 34/12 34/15 35/2 35/15 36/18 42/4 42/24 45/22 47/22 49/15 49/20 57/24 58/5 58/14 58/18 59/3 60/15 61/14 62/1 63/9 63/15 63/25 64/4 65/6 65/10 65/13 67/17 68/4 68/12 69/24 71/18 72/2 72/19 72/24 73/2 73/8 73/12 73/16 73/22 74/2 74/7 75/7 75/8 75/12 77/2 77/11 77/25 79/1 79/18 79/23 80/2 80/7 80/11 81/12 81/15 81/17 82/17 83/6 84/3 85/16 85/19 85/23 86/5 86/15 86/18 88/3 88/7 89/14 90/9 90/13 92/3 93/7 93/10 94/22 95/16 102/18 103/21 106/10 106/22 107/13 107/18 107/24 108/6 109/20 110/3 110/22 113/15 113/19 116/1 116/13 116/18 118/9 121/4 122/1 124/6 124/9 124/12 127/1 127/7 127/10 127/17 127/24 128/1 128/11 128/22 129/13 130/9 130/11 130/23 131/15 131/17 132/10 132/16 133/9 135/7 136/7 138/16 139/21 141/23 141/25 142/18 142/24 146/10 146/23 147/21 150/2 150/19 150/21 151/8 153/20 153/25 154/12 155/7 155/9 156/6 157/12 157/19 157/25 158/20 160/2 162/6 162/11 162/17 164/4 164/17 164/19 165/4 167/24 169/4 170/1 170/18 170/21 170/24 171/3
Dr Rizza's [34] 24/1 33/14 34/24 36/9 36/18 38/4 60/1 61/11 63/3 63/25 65/18 68/9 83/24 91/21 103/3 113/12 115/21 127/2 130/22 138/10 149/9 153/13 155/2 156/15 157/10 158/12 160/7 161/2 161/8 163/17 163/25 168/22 169/24 170/15
Dr Rosemary Biggs [3] 4/22 9/22 45/22
Dr Smith [3] 5/14 127/23 128/11
Dr Smithies [1] 113/16
Dr Trowell [3] 65/19 95/16 133/10
Dr Waiter [4] 19/25 21/10 21/11 55/3
Dr Watt [4] 90/10 90/13 92/3 93/6
Dr Winter [1] 142/14
draft [3] 93/11 120/23 122/8
draw [12] 6/7 26/8 31/6 67/15 73/9 78/13 86/25 105/25 136/24 145/11 156/13 169/3
drawbacks [1] 166/10
drawn [6] 15/5 39/14 75/9 78/22 93/15 98/14
draws [2] 52/5 162/6
dried [35] 7/8 7/9 7/21 7/25 8/8 10/11 10/22 13/11 13/20 13/23 16/16 27/23 28/23 29/17 29/22 30/20 32/25 43/19 43/23 44/1 44/20 46/3 46/6 46/14 47/7 47/8 51/3 51/17 52/9 52/13 52/21 53/12 67/12 100/19 163/16
drop [1] 108/25
dropped [1] 15/1
Drs [3] 27/2 27/24 28/3
Drs Arblaster [1] 27/24
drug [4] 90/18 129/22 145/16 157/16
drugs [2] 23/7 152/6
dubious [1] 108/17
due [12] 1/25 5/8 12/9 38/4 51/6 73/10 77/15 111/21 155/2 159/1 164/12 172/25
Dunton [1] 35/6
during [16] 14/25 15/10 16/11 17/3 60/20 78/8 103/20 114/1 114/8 115/22 143/19 151/4 155/11 155/18 159/23 169/11

E

each [12] 10/21 11/2 11/4 11/5 50/5 97/11 105/24 115/9 116/23 118/11 143/14 148/21
earlier [17] 4/18 13/14 33/5 38/2 38/21 41/25 62/9 69/20 80/24 80/25 85/3 100/2 100/4 127/15 145/20 155/8 171/5
early [28] 1/7 1/9 2/24 9/14 9/20 14/20 18/11 25/25 28/14 30/22 30/22 31/11 31/17 38/17 47/24 62/1 71/18 76/15 109/16 127/10 131/3 151/1 154/6 155/11 156/22 158/1 166/7 172/4
early 1980s [1] 156/22
early May [1] 76/15
early May 1983 [1] 71/18
easier [1] 51/16
easiest [1] 111/6
easily [2] 32/9 40/19
easy [3] 23/8 124/16 132/11
Ebbesen [1] 77/13
economy [1] 23/13
Edinburgh [3] 41/10 43/24 105/3
editorial [1] 158/16
educated [1] 9/7
Edward [1] 172/18
effect [2] 110/1 159/12
effective [5] 17/12 35/18 43/16 44/15 102/2
effectively [6] 8/10 29/1 41/14 70/10 116/19 170/4
effects [1] 103/17
efficacy [2] 39/16 92/15
efficient [1] 53/17
effort [2] 50/13 55/15
efforts [3] 12/9 21/18 164/8
eg [2] 124/25 125/9
eight [1] 168/15
either [5] 21/3 76/22 87/8 117/25 138/4
elapse [1] 94/8
elevated [2] 99/4 106/14
elicit [1] 165/21
eligible [1] 97/20
eliminated [2] 126/17 127/2
Elizabeth [2] 6/17 57/25
else [4] 39/10 107/8 134/23 140/18
elsewhere [3] 19/16 75/13 109/8
Elstree [8] 33/21 41/10 43/23 85/23 105/7 106/16 107/1 107/5
embargo [3] 108/8 109/13 109/15
emerge [3] 132/24 151/12 151/19
emergencies [1] 20/19
emergency [1] 41/13
emerges [4] 38/3 59/17 151/24 152/3
emerging [2] 3/2 61/6
emphasis [1] 78/25
employ [1] 24/20
employed [1] 24/21
enable [3] 21/4 119/14 171/24
enabled [1] 12/24
enclosed [1] 136/12
enclosing [1] 21/9
encourage [2] 93/2 94/11
end [16] 6/7 20/13 61/13 66/23 81/6 82/10 110/6 111/16 113/23 157/13 157/20 162/12 164/5 164/13 164/15 165/15
endangering [1] 24/9
England [8] 28/8 39/9 41/8 66/24 67/10 67/19 158/16 160/2
English [1] 40/11
enormous [2] 23/23 108/7
enough [4] 28/4 40/19 55/11 105/23
enquire [3] 102/20 124/20 126/10
enquired [1] 145/17
enrol [1] 94/17
enrolled [2] 94/20 152/13
ensure [3] 40/15 94/10 137/19
entail [1] 24/13
enter [1] 130/6
entered [1] 119/19
entering [1] 128/4
enterprise [1] 41/4
entire [1] 9/12
entirely [7] 11/15 16/14 34/21 41/16 87/16 128/21 132/11
entities [1] 35/6
entitled [3] 100/9 157/10 163/25
entry [3] 96/19 97/7 164/2
enzymes [1] 155/22
epidemiological [4] 4/11 149/22 149/24 162/12
epidemiology [2] 85/11 121/2
episodes [2] 32/1 159/5
equal [1] 37/23
equally [2] 35/18 53/16
equipment [1] 31/14
equivalent [1] 134/22
error [1] 34/25
escapes [1] 172/16
especially [4] 37/14 90/18 113/1 136/14
essential [1] 23/17
essentially [1] 45/24
establish [2] 80/15 81/20
established [3] 2/9 4/21 98/21
establishment [1] 42/23
estimate [5] 20/24 40/7 41/5 50/4 101/1
estimated [2] 18/6 39/19
estimates [1] 49/2
et [11] 35/24 67/7 98/3 98/3 105/1 140/12 144/3 144/3 144/8 153/20 163/8
et cetera [8] 35/24 98/3 98/3 105/1 140/12 144/3 144/3 153/20
Ethel [1] 5/2
ethical [4] 91/1 92/10 104/18 141/7
ethically [1] 91/13
Europe [1] 74/22
European [3] 76/21 76/24 111/17
evaluate [4] 93/24 94/6 104/17 105/24
evaluated [1] 132/7
evaluating [1] 102/9
evaluation [1] 106/6
even [7] 29/5 82/12 124/25 134/11 137/13 137/13 137/17
event [2] 35/14 148/9
events [1] 85/20
eventually [1] 161/15
ever [4] 16/24 22/23 24/6 117/25
ever-increasing [1] 16/24
every [3] 24/16 78/17 78/22
everybody [1] 151/17
everyone [3] 8/22 22/18 140/18
everything [2] 23/5 41/7
everywhere [1] 39/10
evidence [37] 1/12 1/14 16/3 41/20 41/21 42/6 60/8 69/17 72/12 73/10 74/12 79/12 83/22 95/6 115/1 128/13 132/22 132/24 132/25 137/25 138/6 140/6 141/9 150/9 153/4 153/10 160/9 162/12 163/11 163/20 168/3 168/4 170/1 170/9 172/16 172/18 172/20
evident [1] 105/21
exact [1] 125/8
exactly [1] 57/24
examination [1] 97/25
example [8] 6/16 14/6 19/4 19/24 57/23 61/25 109/19 151/5
examples [1] 6/15
excellent [1] 16/22
Excelsior [1] 90/6
Excelsior Hotel [1] 90/6
except [2] 66/6 105/16
exchange [4] 21/7 80/1 102/14 105/5
exchanging [1] 94/7
exclusively [1] 81/23
exemption [2] 87/10 89/25
exercising [1] 6/5
exhaustive [1] 3/11
existed [3] 161/23 161/24 172/5
existing [1] 112/14
exists [1] 18/4
expect [1] 35/10
expectation [2] 25/21 97/13
expected [1] 92/22
expedite [2] 41/7 90/2
expedition [1] 97/3
expenditure [5] 23/7 23/23 23/25 25/14 107/25
expense [1] 110/15

E

expensive [4] 17/9 23/19 44/16 57/2
experience [2] 31/13 64/17
experiencing [2] 16/4 16/12
experiments [1] 92/17
expert [11] 3/17 6/4 30/17 42/23 43/12 45/4 45/12 45/19 47/21 47/25 153/13
expertise [1] 147/9
experts [2] 162/16 162/17
explain [4] 16/19 135/9 148/9 154/4
explaining [2] 97/17 127/24
explains [3] 10/20 12/5 143/2
explanation [1] 160/18
explored [2] 45/15 48/4
exploring [1] 80/10
exposed [3] 88/25 100/19 165/8
exposure [5] 100/12 101/19 102/5 104/15 106/3
express [1] 111/12
expressed [9] 22/6 58/21 84/18 107/18 113/12 122/12 131/15 132/10 147/23
expressing [3] 23/20 25/19 110/24
expression [1] 69/2
expressly [2] 24/23 75/7
extend [1] 101/16
extended [1] 4/16
extensively [1] 17/13
extent [14] 51/25 88/21 90/25 109/2 126/23 130/25 134/4 151/25 152/4 161/24 163/10 165/20 167/23 168/2
external [1] 140/11
extra [1] 128/16
extract [1] 149/16
extraction [1] 24/18
extreme [1] 131/6
extremely [2] 166/3 167/7
eye [1] 48/6

F

faced [2] 109/4
130/15
fact [24] 20/15 22/7 22/8 30/19 31/7 33/25 36/7 46/18 47/12 49/13 51/7 53/1 54/9 56/9 56/14 59/14 90/4 92/23 108/18 124/3 136/19 145/12 159/1 165/3
factor [181]
factor IX [11] 3/15 3/25 6/20 12/2 15/9 50/17 80/21 88/11 111/1 112/2 112/15
factor VIII [137] 7/19 7/24 10/12 10/25 13/2 13/4 13/8 13/8 13/11 14/3 14/15 15/3 15/6 18/5 20/9 21/20 21/22 22/17 22/21 23/2 23/16 24/6 24/15 25/10 25/13 25/13 25/15 25/18 25/20 29/16 30/7 30/19 30/20 34/3 34/14 34/16 36/23 37/1 37/10 37/14 37/15 38/6 43/19 44/19 50/3 50/20 50/22 53/14 55/8 55/13 56/1 56/5 56/11 56/15 56/17 57/2 57/5 58/7 58/25 59/19 62/16 63/2 63/5 64/24 66/10 67/5 69/9 69/11 69/13 69/22 74/3 74/14 74/16 75/11 78/7 81/10 81/13 84/11 84/16 87/3 88/10 89/4 90/14 90/18 93/14 93/18 93/21 95/2 95/5 95/18 95/23 96/17 98/19 99/25 100/12 100/24 101/7 101/11 102/23 103/6 104/4 104/12 104/16 104/24 105/2 105/17 106/4 108/10 108/14 108/18 109/14 109/24 110/1 111/1 111/25 113/24 142/6 142/7 154/12 154/15 154/18 154/25 156/23 159/17 162/20 163/16 163/19 164/18 164/22 165/25 166/3 166/14 166/15 167/3 168/10 169/21 169/22
Factor VIII-related [1] 3/22
Factorate [4] 34/19 35/25 36/6 36/11
factors [2] 14/9 39/7
facts [1] 148/19
fair [5] 32/24 73/9 73/16 79/17 155/12
fairly [4] 5/14 33/6 80/8 136/9
faith [1] 152/1
fall [1] 14/12
fallen [1] 12/15
familiar [1] 150/1
family [3] 9/8 36/18 165/13
far [17] 20/15 23/8 24/8 36/21 37/11 37/21 38/6 41/17 78/1 82/24 108/10 113/21 149/12 158/25 160/9 160/10 168/3
favour [1] 55/12
fear [1] 140/23
feasible [1] 56/17
feature [1] 56/6
February [4] 18/19 31/4 45/2 45/6
feel [12] 17/24 20/22 24/14 41/10 44/18 44/20 55/8 55/13 65/1 108/7 114/14 126/10
feeling [4] 36/2 65/8 83/11 153/5
feels [1] 81/3
felt [3] 27/5 28/7 122/13
female [3] 120/5 150/11 150/14
few [21] 22/5 32/18 41/21 49/6 49/11 50/6 52/23 70/9 72/11 89/1 90/11 91/11 97/10 100/8 100/21 112/14 132/15 147/11 159/1 160/15 167/20
field [1] 66/1
Fifteen [1] 120/17
fifth [1] 152/11
figure [3] 20/18 20/23 149/10
figures [8] 15/5 15/13 112/20 121/10 129/3 129/9 129/11 130/7
file [3] 137/9 137/16 144/17
files [3] 137/17 137/19 137/22
filled [1] 146/17
film [1] 28/20
final [3] 142/1 153/2 153/12
finalised [1] 40/24
finally [6] 25/4 83/5 91/15 132/3 167/20 171/21
financial [5] 19/12 22/11 45/8 57/12 109/3
find [14] 35/17 36/25 45/17 63/19 70/2 78/10 88/20 89/7 108/24 130/25 136/2 137/1 137/6 137/21
finding [2] 67/11 80/21
findings [2] 67/20 161/25
firm [5] 20/8 20/9 56/15 94/4 94/10
firmly [1] 80/15
firms [4] 46/6 47/25 93/23 94/18
first [49] 11/21 14/2 14/7 18/13 18/18 19/11 24/7 31/13 36/6 37/2 37/25 45/18 56/8 58/21 59/16 60/17 61/18 62/17 63/9 66/23 74/5 75/11 78/13 80/3 88/5 94/5 94/16 95/3 95/22 96/4 100/12 100/20 101/8 101/18 104/15 107/15 115/17 119/4 124/3 137/18 138/12 151/21 156/24 158/21 161/9 164/5 165/15 169/12 170/22
firstly [1] 160/14
fit [1] 157/6
five [6] 38/21 51/4 66/9 81/4 123/12 164/5
flagged [2] 25/22 147/20
Fletcher [4] 5/11 65/20 95/16 136/19
flicked [1] 48/7
fluids [2] 140/8 140/15
focal [1] 62/4
focus [5] 1/4 6/5 6/6 8/4 172/20
fold [1] 167/13
follow [9] 18/25 97/12 99/2 99/13 110/20 116/20 134/10 136/6 155/18
follow-up [4] 99/2 99/13 134/10 155/18
followed [5] 78/9 79/11 79/20 84/12 98/1
following [15] 7/5 15/8 15/24 69/7 80/11 100/23 116/5 116/18 123/25 131/16 135/13 151/18 152/19 153/18 162/2
follows [5] 34/18 90/13 125/23 129/17 170/14
Forbes [2] 110/23 111/9
force [2] 3/24 66/13
forced [1] 17/20
foreign [1] 58/25
form [26] 1/24 24/21 44/3 50/9 59/19 67/15 67/22 88/14 88/19 93/11 98/15 107/11 119/8 126/7 143/21 144/3 144/10 144/11 144/14 144/15 144/23 144/25 145/7 146/20 146/22 147/4
formalise [1] 90/20
formed [1] 72/5
former [3] 71/6 104/22 146/9
forms [9] 99/12 143/15 143/17 143/20 143/24 144/1 144/9 145/3 145/22
forthcoming [1] 138/20
forward [3] 81/7 82/9 172/23
forwarded [1] 128/7
found [22] 17/15 32/11 57/8 61/3 66/9 80/16 81/24 120/12 120/17 120/18 127/11 130/16 131/5 133/16 134/10 134/12 134/22 136/13 136/16 136/18 149/12 165/17
four [6] 24/10 88/9 104/6 108/11 116/8 157/12
fourth [2] 105/9 152/8
fractionated [2] 12/16 12/25
fractionation [13] 2/8 5/3 12/24 25/8 41/9 51/22 55/16 59/6 70/6 70/19 71/4 159/18 167/16
fractions [3] 7/25 41/8 159/20
frame [2] 1/5 4/5
Francisco [1] 66/21
free [12] 6/16 17/15 28/24 29/4 32/14 32/17 80/9 83/17 86/21 112/18 159/20 172/21
freedom [4] 23/2 23/9 92/19 93/3
freely [1] 56/20
freeze [35] 7/8 7/9 7/21 7/25 8/8 10/11 10/22 13/11 13/20 13/23 16/16 27/23 28/23 29/17 29/22 30/20 32/25 43/19 43/23 44/1 44/20 46/3 46/6 46/14 47/7 47/8 51/3 51/17 52/9 52/13 52/21 53/12 67/12 100/19 163/16
freeze-dried [31] 7/8 7/9 7/21 7/25 10/11 10/22 13/20 13/23 16/16 28/23 29/17 29/22 30/20 32/25 43/19 43/23 44/1 44/20 46/3 46/6 46/14 47/7 47/8 51/3 51/17 52/9 52/13 53/12 67/12 100/19 163/16
freezers [1] 32/20
frequency [1] 52/24
frequent [2] 14/2 60/11
fresh [3] 7/7 7/13 31/19
Friday [1] 1/1
from [254]
frozen [4] 7/7 7/13 31/19 32/11
fulfil [1] 125/16
fulfilled [1] 92/12
full [5] 2/4 9/5 68/24 144/2 169/25
full-blown [1] 68/24
fullest [1] 128/17
fully [2] 87/17 97/22
function [12] 5/22 6/4 61/22 61/23 98/2 99/3 125/16 134/9 134/11 136/22 155/21 156/1
Fund [1] 121/1
funded [1] 21/4
funding [4] 19/4 22/2 108/1 110/4
funds [1] 23/22
further [41] 1/16 1/22 7/12 23/17 30/4 45/13 50/6 57/21 57/23 66/16 73/10 81/15 82/16 83/21 84/1 91/19 92/2 93/6 97/10 100/14 103/8 103/18 107/25 118/4 123/20 123/23 135/23 137/19 140/2 142/22 146/2 147/2 147/11 150/4 152/18 168/8 168/15 168/16 170/2 170/11 171/25
Furthermore [1]

F

Furthermore... [1] 114/25
future [10] 45/4 74/8 88/19 89/17 92/15 98/17 102/21 106/4 127/18 138/23

G

Galbraith [4] 77/23 85/3 85/7 150/2
Galbraith's [1] 85/4
Gallo [1] 161/25
gather [2] 113/21 114/2
gave [8] 41/21 42/7 110/13 126/4 138/6 153/9 158/22 161/13
general [12] 3/19 6/6 8/19 9/1 37/9 60/8 61/19 71/13 109/1 124/17 124/17 142/14
generally [5] 5/10 18/16 71/11 100/5 154/15
George [2] 43/4 59/9
German [3] 75/4 75/15 76/17
Germany [2] 105/12 162/11
get [6] 12/19 52/10 61/11 68/8 87/22 162/8
getting [2] 19/14 21/18
Giangrande [1] 1/8
give [11] 13/25 22/2 24/2 47/24 74/12 91/13 91/24 103/14 132/8 134/19 171/24
given [26] 24/17 35/10 37/1 56/20 60/1 61/5 65/1 75/13 76/15 79/1 93/17 95/18 97/21 105/12 115/10 126/2 131/5 132/23 133/21 134/3 135/1 142/17 145/4 160/13 160/19 167/20
gives [13] 12/3 14/6 31/10 36/7 36/19 41/5 65/5 83/22 87/11 100/14 102/10 154/2 170/1
giving [4] 1/14 27/11 51/25 172/19
glad [2] 22/18 90/16
globulin [2] 7/9 7/10
GMC [1] 123/7
go [114] 6/21 7/2 7/11 8/12 9/25 11/19 11/20 11/23 14/23 17/1 18/10 19/18 21/6 26/6 26/16 28/18 29/12 31/1 31/5 31/9 31/15 32/21 33/10 34/10 35/14 36/14 45/3 46/11 48/5 48/11 49/22 50/15 50/24 51/13 52/10 53/18 54/9 55/2 55/15 58/19 59/2 59/8 60/14 62/8 62/11 65/17 65/22 66/22 68/3 71/17 72/4 83/1 83/5 84/5 85/1 85/21 86/11 87/5 87/13 93/8 94/17 103/2 106/8 111/7 112/5 112/19 113/3 113/9 113/14 115/25 116/12 116/17 120/1 120/22 121/9 125/22 130/10 131/16 132/2 133/3 135/5 135/23 141/10 141/24 146/3 149/15 149/16 149/23 150/4 153/16 153/17 153/23 153/24 154/9 154/23 155/4 155/5 157/9 157/11 157/24 158/15 158/19 159/25 161/18 162/2 162/8 163/3 163/13 163/24 164/2 164/16 164/19 168/25 169/15
Godber [2] 38/23 43/4
goes [16] 16/19 26/14 37/16 39/23 43/15 53/7 53/23 70/1 89/6 108/12 115/5 125/17 130/19 154/20 165/24 168/9
going [12] 8/13 53/10 59/12 59/13 74/6 74/25 76/7 80/24 83/12 141/10 151/15 153/23
good [14] 12/22 17/24 22/16 30/1 30/9 30/13 40/3 56/11 68/20 73/14 91/14 134/12 137/17 169/17
good-quality [1] 56/11
got [4] 8/8 48/9 49/24 133/11
Government [2] 23/14 45/25
GP [1] 133/18
GPs [1] 134/20
gradual [1] 114/1
grandsons [1] 137/15
grant [2] 16/15 123/12
Grant's [1] 31/20
granted [1] 46/5
grateful [1] 109/12
great [11] 21/18 39/16 40/21 41/22 44/8 70/7 129/3 159/13 166/8 166/13 166/25
greater [9] 46/20 52/17 52/19 54/22 109/4 110/15 159/10 160/24 162/22
greatest [1] 109/7
greatly [4] 25/5 50/9 52/25 114/13
Green [1] 35/7
ground [1] 152/6
ground-breaking [1] 152/6
grounds [2] 117/24 138/23
group [23] 3/17 4/8 4/10 42/23 45/4 45/12 45/17 45/19 47/21 47/25 66/9 72/5 82/20 91/10 96/16 100/17 101/2 104/18 121/25 122/2 122/12 128/17 131/4
groups [5] 3/9 3/21 27/19 157/14 157/20
guarantee [1] 88/18
Guardian [1] 110/9
guidance [1] 34/13
guide [1] 36/7
guidelines [3] 78/3 78/15 169/1
Gunson [1] 150/2

H

had [96] 2/7 5/21 8/10 19/13 19/14 20/4 25/22 26/21 26/21 27/2 27/24 28/7 29/15 31/23 33/17 34/24 36/17 37/23 38/5 38/19 42/15 55/18 55/22 64/18 66/1 66/8 66/16 67/12 67/19 76/1 76/15 78/17 79/14 84/11 92/15 92/21 93/18 95/20 97/9 101/13 102/4 106/11 106/13 108/1 110/3 110/23 111/18 111/19 115/15 115/17 117/1 117/4 117/16 117/21 118/13 118/16 118/24 119/1 121/12 121/13 122/11 122/12 122/13 122/15 123/4 126/19 126/21 127/8 127/13 128/1 128/24 129/25 132/18 132/20 136/10 137/9 138/17 139/5 140/20 150/21 151/25 152/12 153/6 153/7 155/20 159/2 160/15 160/20 164/7 164/13 165/13 166/6 166/10 166/13 167/12 168/12
hadn't [1] 85/5
haematologist [1] 19/9
haematologists [2] 8/20 19/7
haematology [1] 19/8
haemophilia [153] 1/5 2/6 2/11 3/1 3/4 3/17 4/2 4/18 4/21 5/9 5/16 6/14 6/23 8/24 9/16 9/23 10/7 10/16 12/1 14/13 14/22 18/7 19/20 20/6 20/10 23/19 23/25 25/25 26/12 26/24 31/22 33/8 38/20 38/23 39/2 41/18 42/18 43/7 43/25 45/5 45/20 50/11 50/21 50/24 52/6 56/2 56/6 58/4 58/22 58/24 59/20 62/10 63/24 64/19 64/22 66/4 69/8 73/1 76/13 76/20 78/2 78/14 78/17 78/21 78/22 80/20 81/25 82/1 84/19 84/22 86/3 87/1 87/20 88/4 88/6 90/24 93/13 96/13 101/6 101/17 102/22 104/1 104/2 107/4 107/7 108/9 109/9 110/25 111/12 111/16 111/24 112/1 112/8 112/9 113/8 115/24 116/7 116/23 118/12 121/3 121/8 121/14 121/14 123/14 123/18 124/2 125/25 129/1 129/2 129/4 129/5 129/8 129/16 134/6 134/23 134/24 135/4 135/11 138/7 138/16 139/22 139/23 141/3 141/16 141/18 142/2 142/25 143/4 146/1 147/18 148/13 148/14 148/16 148/21 150/3 150/22 150/24 150/25 151/8 151/14 152/2 154/1 154/3 156/12 156/16 158/5 162/16 162/17 163/25 164/7 166/25 167/3 170/8
haemophilia A [12] 10/7 10/16 14/13 14/22 33/8 59/20 66/4 81/25 102/22 111/24 121/14 129/4
haemophilia B [6] 12/1 80/20 82/1 112/1 121/14 129/5
Haemophilia Society [1] 151/8
haemophiliac [9] 9/5 9/13 74/25 75/20 76/2 118/23 137/11 140/4 140/23
haemophiliacs [54] 7/7 26/19 64/10 68/20 72/15 77/17 77/21 78/1 78/6 80/18 81/22 90/22 90/23 92/9 100/11 100/17 102/4 103/15 107/9 111/18 111/19 116/4 116/22 118/8 120/5 120/14 121/7 121/11 123/19 129/18 130/13 131/2 136/13 139/12 150/13 155/5 155/13 155/18 155/20 155/25 156/13 156/18 157/2 157/4 157/18 157/23 158/4 158/23 159/2 160/15 162/20 164/2 164/6 164/10
haemophilic [9] 7/8 7/10 8/17 16/13 21/19 39/15 43/17 55/10 137/19
haemorrhage [5] 159/9 159/11 160/22 160/24 162/21
haemostasis [3] 3/24 4/1 7/20
half [14] 9/25 17/2 17/3 18/7 19/11 26/11 50/20 61/18 86/5 103/16 111/19 115/17 162/9 163/4
half-life [1] 103/16
halfway [9] 13/6 22/25 27/21 30/5 50/16 65/22 89/20 149/24 161/6
hand [4] 48/25 56/3 86/13 86/13
handful [3] 3/10 88/6 151/12
handled [6] 119/18 143/7 143/8 143/12 146/6 146/8
handling [3] 146/5 166/23 167/5
handwriting [1] 92/4
handwritten [1] 120/20
happen [1] 59/12
happened [1] 106/20
harder [1] 22/22
has [78] 7/19 9/3 12/7 12/8 12/12 12/15 12/24 13/7 13/8 13/9 17/14 17/15 20/9 22/9 23/2 24/18 25/5 34/7 34/12 37/5 37/21 50/9 50/10 50/13 52/16 54/21 56/15 62/21 62/22 64/22 64/24 65/4 68/19 77/23 78/21 79/1 79/10 81/12 82/5 82/22 84/13 88/22 89/9 90/25 91/2 98/23 100/17 108/6 111/21 114/24 114/25 120/20 123/9 124/12 124/17 124/24 128/10 131/1 132/25 133/23 134/20 135/10 135/19 138/5 138/24 138/25 141/13 142/6 143/5 143/8 145/6 147/21 147/23 151/18 155/7 168/4 169/13 170/6
have [223]
haven't [4] 97/5 97/22 134/22 149/12
having [7] 27/7 32/20 69/24 73/10 76/12 108/14 139/24
HCDO0000003 [2] 93/9 153/15
HCDO0000135 [1] 100/6
HCDO0000248 [1] 142/23
HCDO0000252 [1] 87/23
HCDO0000270 [1] 94/25
HCDO0000394 [1] 58/17
HCDO0000413 [1] 84/3
HCDO0000581 [1] 60/14
HCDO000558 [1] 65/16
HCV [25] 128/19 128/23 128/25 129/7 130/12 130/16 131/1 131/2 131/19 131/22 131/25 132/2 132/4 132/7 132/12 132/23 133/6 133/8 133/16

H

HCV... [6] 133/17 136/12 136/23 152/17 171/15 171/20
he [113] 3/11 3/13 3/16 3/17 3/18 3/20 3/21 4/1 4/2 4/6 4/9 4/10 6/5 6/5 7/15 7/16 7/21 16/19 22/4 22/24 22/25 23/6 24/10 24/23 25/3 31/19 31/21 32/19 36/20 36/23 37/1 37/3 37/4 37/16 37/22 37/23 41/21 43/9 43/15 44/11 57/24 59/11 64/18 66/1 69/5 70/1 75/25 76/9 76/12 76/12 76/14 76/14 76/15 76/18 76/19 76/22 77/3 77/13 77/16 81/3 85/5 85/23 86/1 90/15 92/13 101/25 102/10 103/8 108/12 113/20 114/5 114/19 115/5 124/15 125/17 126/12 128/1 128/6 128/10 129/15 130/19 130/24 142/5 142/5 142/6 143/13 148/18 149/11 150/23 150/24 151/9 154/20 154/23 155/24 162/6 162/15 163/1 163/20 165/5 165/11 165/12 165/24 166/3 166/11 166/18 166/22 167/9 168/9 168/16 169/13 169/16 169/20 170/2
he'll [1] 63/19
he's [3] 31/12 72/2 156/15
head [1] 5/3
headed [8] 51/2 68/14 93/13 142/24 149/18 154/10 155/5 156/11
heading [17] 7/3 10/1 26/7 29/12 34/3 51/14 84/6 87/14 87/19 96/24 96/24 98/8 122/6 146/4 149/24 156/14 157/24
health [17] 9/2 19/23 20/1 28/1 30/16 38/24 42/5 43/12 58/15 68/13 106/23 108/3 113/17 121/20 121/23 129/14 138/15
Health on [1] 42/5
hear [2] 71/14 90/16
heard [9] 28/25 69/17 73/10 75/2 85/5 132/22 138/1 147/16 160/9
hearing [2] 1/8 1/16
heat [38] 75/4 75/14 86/8 88/14 90/9 90/14 102/23 103/6 103/12 103/14 103/24 104/23 106/7 106/18 106/21 107/10 107/19 107/24 108/9 108/13 108/16 108/21 108/23 109/14 109/17 110/4 110/7 110/16 111/1 111/3 112/4 112/15 113/5 115/16 156/20 163/18 163/22 169/14
heat' [2] 104/13 104/22
heat-treated [30] 75/4 86/8 90/9 102/23 103/12 103/14 103/24 106/7 106/18 106/21 107/10 107/19 107/24 108/9 108/13 108/16 108/21 108/23 109/14 109/17 110/4 111/1 111/3 112/4 112/15 115/16 156/20 163/18 163/22 169/14
heated [11] 104/21 105/2 105/10 107/16 109/23 111/22 114/15 114/16 115/5 169/18 169/22
Heathrow [1] 90/6
heavily [1] 81/22
held [8] 31/3 77/15 107/5 121/25 124/1 124/3 147/6 148/22
Helen [1] 64/11
Helen Chappell [1] 64/11
help [3] 125/2 128/17 131/11
helper [1] 67/13
helps [1] 154/4
Hemofil [8] 18/15 18/19 34/18 35/23 36/5 36/10 61/1 106/13
hence [1] 134/8
Henry [56] 6/21 7/2 8/8 9/21 9/25 11/19 12/18 15/22 16/7 26/7 26/16 28/18 31/1 31/5 31/9 32/3 34/11 36/14 37/18 43/2 48/11 49/14 50/25 51/1 51/13 52/10 62/8 62/11 65/15 73/4 84/5 86/12 90/12 102/15 111/7 112/6 113/14 115/25 120/22 121/22 130/23 133/3 148/8 149/4 149/14 149/17 149/23 153/15 153/17 153/23 155/6 157/9 158/19 160/1 161/5 162/2
hepatitis [115] 5/23 17/16 17/17 17/18 46/20 46/22 46/25 47/3 47/5 52/18 52/20 52/24 54/6 54/8 59/25 60/6 60/8 60/13 61/5 61/11 61/16 61/19 61/21 62/2 62/3 62/3 62/15 62/23 63/4 64/6 65/14 65/21 67/21 74/3 74/9 86/17 86/21 86/21 87/3 87/7 88/12 89/9 89/13 89/23 90/5 90/17 90/25 93/14 93/15 94/21 94/25 95/1 95/4 95/8 95/11 95/11 95/13 95/21 96/3 97/10 97/12 97/14 98/4 98/6 98/7 98/11 98/12 98/16 99/5 99/5 99/25 100/3 100/5 100/11 100/16 100/18 100/23 100/24 101/2 101/8 101/18 102/2 102/7 102/8 102/22 103/7 104/15 105/1 106/9 106/12 114/18 115/2 115/7 127/21 127/22 127/25 128/14 135/11 138/22 139/8 139/17 144/4 144/7 144/8 154/14 154/18 155/5 155/12 155/17 156/8 156/13 156/18 156/23 170/20 171/12
hepatitis B [11] 17/18 46/22 47/3 54/8 61/21 88/12 95/11 98/7 99/5 139/8 139/17
hepatitis C [3] 127/22 127/25 135/11
hepatitis-free [1] 86/21
hepatitis-reduced [7] 86/17 86/21 87/7 90/5 95/4 99/25 100/3
hepatitis-safe [2] 87/3 89/13
her [12] 5/19 7/16 11/16 11/17 13/18 15/5 19/24 20/24 41/14 68/17 68/18 153/6
here [30] 8/13 13/17 14/19 25/18 26/20 29/5 30/17 31/10 36/2 48/1 48/10 60/14 64/11 70/10 70/13 75/12 81/3 82/17 83/7 86/22 94/25 103/4 107/18 113/19 122/16 130/10 131/19 153/18 161/19 172/20
herself [1] 32/15
heterosexual [1] 150/10
high [3] 40/10 68/5 80/19
higher [3] 11/6 14/4 47/7
highest [1] 100/18
highlights [1] 161/23
highly [1] 152/7
him [10] 71/15 71/16 74/24 75/8 75/19 77/19 78/8 90/15 126/2 136/8
himself [5] 3/8 9/8 65/1 73/12 137/14
hinder [1] 89/16
his [29] 1/11 1/12 4/5 4/15 4/24 6/9 9/6 9/8 31/13 41/23 61/12 61/14 63/9 63/12 64/24 65/7 65/10 70/24 74/25 75/20 76/20 85/20 86/1 87/11 91/23 115/5 137/15 153/25 165/4
histology [1] 156/2
historical [1] 11/14
history [3] 150/8 151/18 154/1
hitherto [1] 106/19
HIV [54] 4/14 6/3 86/14 114/16 114/17 114/25 116/21 117/4 117/22 118/2 118/7 118/16 118/25 120/4 121/5 121/13 121/21 122/6 122/10 122/14 123/13 123/17 123/22 124/1 124/3 124/23 125/13 126/2 126/19 127/11 127/13 128/12 129/11 129/17 129/18 130/8 136/16 138/22 139/2 139/8 139/16 140/1 140/5 140/7 140/16 140/24 144/19 152/17 153/14 155/10 159/24 171/12 171/14 171/20
HIV infection [1] 126/2
HIV positive [1] 123/13
HIV-infected [1] 123/22
HIV-related [1] 139/2
HIV/AIDS [1] 122/6
HIV/hepatitis B [1] 138/22
holding [1] 127/9
holiday [1] 74/19
home [43] 13/17 13/20 13/21 13/25 14/2 14/4 14/7 14/11 14/14 14/20 21/1 24/24 27/11 28/19 28/20 29/4 29/6 30/1 30/24 32/6 32/12 32/18 32/20 33/2 33/3 33/5 33/8 33/11 33/18 33/24 34/4 34/6 34/8 44/10 45/11 53/8 54/1 142/7 142/17 144/3 159/6 159/8 166/16
homes [1] 29/10
homosexual [1] 112/22
homosexuals [1] 157/14
Honourable [1] 58/19
hope [12] 23/3 23/13 70/7 82/8 82/9 89/14 93/2 94/11 98/9 128/16 155/8 172/24
hopefully [2] 80/20 83/21
horizon [1] 25/5
hospital [17] 4/20 5/17 6/17 8/20 9/1 19/16 27/11 28/24 58/1 108/5 131/18 135/7 139/10 140/19 142/16 166/17 172/21
hospitals [3] 6/15 52/7 84/22
hotel [3] 68/3 90/6 160/6
hours [1] 31/24
household [1] 145/18
how [30] 7/13 9/12 19/13 21/14 21/17 26/14 31/11 40/18 49/2 56/4 57/12 79/23 87/11 91/21 93/1 98/4 99/11 99/12 124/20 126/21 134/4 134/15 134/24 143/13 147/3 154/2 158/12 170/16 171/16 171/19
however [12] 6/12 22/22 47/12 63/23 111/23 125/2 125/11 127/15 138/21 140/13 141/13 155/18
HSOC0001272 [1] 73/4
HSOC0002719 [1] 92/3
HSOC0022512 [1] 6/21
HT [1] 34/4
HT' [1] 104/12
HTLV [9] 86/6 111/20 112/21 112/24 115/23 116/3 116/6 150/14 161/15
HTLV-III [9] 86/6 111/20 112/21 112/24 115/23 116/3 116/6 150/14 161/15
hub [1] 141/2
hugely [1] 141/15
human [19] 7/8 7/21 7/24 8/1 8/9 13/2 16/14 16/16 17/6 39/3 39/7 44/14 46/3 54/14 55/8 56/11 57/4 62/16 88/21
human AHG [1] 8/9
hundred [1] 120/11
hurry [1] 36/4
husband [1] 153/6
Hyland [5] 15/17 17/8 28/2 34/7 44/12
hypothesis [2] 66/14 66/16

I

I agree [1] 92/9
I am [8] 21/13 21/16 74/23 114/8 125/15 125/18 130/15 158/21
I and [1] 74/11
I anticipate [1] 1/23
I ask [1] 36/13
I attended [1] 40/1
I can [6] 42/25 83/13 113/21 135/9 137/1 148/9
I cannot [1] 158/8
I certainly [1] 91/15
I did [1] 124/14
I discussed [1] 64/10
I do [6] 20/22 23/10 73/17 83/11 91/13 126/13
I don't [6] 18/23 45/13 48/24 48/24 93/7 168/4
I draw [1] 31/6
I estimate [1] 40/7
I feel [3] 55/8 65/1 114/14
I found [1] 136/13
I gather [1] 114/2

F:

I
I had [2] 20/4 92/15
I have [8] 39/6 39/19 40/3 126/9 131/5 132/6 139/5 149/5
I haven't [1] 149/12
I hope [5] 23/13 70/7 82/8 128/16 155/8
I indicated [1] 141/5
I just [5] 34/23 86/7 140/25 156/13 172/24
I know [1] 108/6
I leave [1] 58/10
I look [2] 81/7 172/23
I made [1] 155/8
I mean [1] 2/17
I mentioned [1] 131/20
I named [1] 153/20
I note [1] 99/16
I personally [1] 115/11
I received [1] 64/16
I referred [2] 76/16 79/13
I said [1] 103/4
I say [3] 28/16 73/15 83/20
I see [2] 19/11 91/1
I shall [1] 114/6
I should [7] 1/18 74/17 86/25 103/13 129/7 152/16 155/7
I showed [1] 145/20
I sincerely [1] 23/3
I suppose [1] 71/10
I talk [1] 138/9
I thank [1] 92/7
I think [39] 8/4 9/24 33/23 35/25 38/24 41/23 42/4 45/3 47/10 48/22 49/13 54/20 58/6 60/2 60/7 68/21 73/18 76/24 77/22 81/8 82/22 85/1 86/10 90/22 91/3 91/8 99/18 116/25 125/15 133/25 137/3 145/5 145/14 151/17 155/11 159/1 163/5 169/23 170/4
I trust [1] 136/2
I understand [2] 108/18 124/16
I want [2] 149/16 151/11
I wanted [2] 153/12 169/24
I was [5] 43/11 48/18 90/16 132/7 137/8
I will [4] 1/12 1/19 6/7 172/25
I won't [9] 14/23 19/18 57/21 59/8 68/3 106/8 116/12 127/3 154/7
I wonder [1] 110/17
I would [8] 24/19 36/5 38/25 125/10 126/10 126/14 128/8 140/17
I write [2] 102/20 140/3
I'd [2] 76/11 76/24
I'll [11] 3/9 18/22 26/7 33/25 42/1 61/1 61/13 65/11 85/19 86/3 88/5
I'm [18] 8/13 16/8 20/2 48/9 49/12 49/23 53/4 53/7 58/2 77/23 81/18 92/3 93/7 97/2 125/13 141/10 151/15 153/23
I've [8] 1/13 3/3 16/1 48/9 54/24 128/25 138/17 149/9
ICL [1] 143/9
ideal [3] 23/16 24/13 32/9
identified [7] 81/12 98/6 135/21 152/23 152/24 170/5 170/13
identifies [1] 163/20
identify [1] 94/12
if [185]
Ill [9] 86/6 111/20 112/21 112/24 115/23 116/3 116/6 150/14 161/15
ill [1] 9/7
ill-educated [1] 9/7
illness [3] 39/14 144/15 155/15
immediate [1] 57/16
immediately [1] 109/13
immune [3] 64/9 65/24 80/22
immunity [1] 80/10
immuno [8] 15/17 17/9 17/13 18/5 27/25 34/7 44/13 70/3
immuno-suppressed [1] 70/3
immunological [1] 81/21
Immunologist [1] 64/11
immunosuppression [1] 70/21
impact [5] 54/7 54/8 107/6 112/7 165/12
impasse [1] 57/17
impecuniosity [1] 22/10
Imperial [2] 121/1 121/1
implicated [2] 66/12 75/2
implications [7] 70/5 70/18 70/25 74/14 87/1 112/20 167/21
import [2] 73/23 87/9
importance [1] 139/9
important [25] 26/18 27/5 39/10 68/22 69/3 69/6 70/5 70/18 79/7 88/2 88/20 89/2 89/7 94/10 95/5 101/1 109/24 111/15 132/4 141/15 144/22 161/8 163/7 163/17 166/10
importation [2] 73/19 77/6
imported [8] 72/13 105/17 111/23 164/18 164/21 164/23 166/7 168/17
importing [1] 46/6
imposed [1] 23/18
impression [2] 158/24 160/7
improving [1] 59/4
Imunin [1] 34/19
in' [1] 114/8
inactivate [1] 101/23
inactivating [1] 102/2
inadequate [2] 44/7 50/22
inception [1] 156/16
incidence [13] 47/5 48/15 54/13 60/19 64/5 100/5 100/10 100/18 101/2 101/18 106/13 121/6 155/14
incident [1] 109/5
include [12] 26/2 74/17 95/7 96/12 96/15 102/24 103/5 119/13 121/4 133/9 150/1 150/10
included [4] 14/11 142/10 157/15 157/21
includes [3] 94/21 122/1 142/4
including [12] 26/4 47/22 65/8 72/2 73/22 75/14 85/16 122/3 149/21 165/1 170/10 170/18
inclusion [4] 94/12 97/4 102/21 147/18
incomplete [3] 138/4 141/12 153/7
increase [8] 12/8 13/7 13/21 13/22 42/18 44/19 52/24 167/13
increased [6] 12/8 19/14 25/6 25/21 30/2 50/9
increasing [9] 14/22 16/12 16/24 29/25 30/9 33/7 112/23 130/15 159/23
incubation [1] 68/6
incur [1] 107/25
indeed [7] 6/14 8/22 9/14 59/16 67/18 79/3 92/7
indicate [1] 1/13
indicated [5] 3/3 99/8 104/13 106/15 141/5
indicates [1] 48/14
indication [2] 91/14 103/18
individual [12] 8/18 11/6 69/19 83/1 90/2 120/3 126/20 127/8 142/20 151/13 152/12 153/3
individuals [8] 9/15 69/17 120/25 123/22 125/4 138/3 138/6 152/22
inevitably [1] 141/12
infamous [1] 87/22
infected [12] 110/13 121/21 122/2 122/4 123/22 125/9 125/13 126/21 130/8 130/16 140/7 150/15
infection [14] 92/20 93/4 112/21 112/25 114/18 124/19 125/15 126/2 126/9 126/11 140/8 140/9 140/16 170/16
infections [3] 3/2 130/12 152/10
infectious [1] 132/4
infective [1] 66/14
infectivity [6] 88/17 88/21 89/4 95/3 95/10 96/7
infer [3] 79/17 80/6 111/2
inference [5] 73/9 73/16 84/15 145/10 145/14
inferentially [2] 116/25 147/22
inferior [1] 108/15
Infirmary [2] 5/17 19/9
influence [4] 4/15 23/15 45/25 171/3
influencing [1] 45/24
information [81] 12/3 28/5 49/12 63/17 63/19 65/5 70/24 72/7 78/3 78/15 78/18 78/19 79/3 79/4 91/19 94/7 97/21 100/15 101/20 104/2 116/5 116/11 117/6 117/13 118/1 118/19 118/22 119/7 119/18 119/24 120/3 120/4 120/8 123/20 126/9 133/15 133/21 134/3 135/1 135/2 135/3 136/21 141/10 141/19 142/8 142/19 143/3 143/5 143/8 143/11 143/15 143/21 144/9 144/12 145/8 145/15 145/18 145/23 146/6 146/7 146/19 146/23 146/25 147/2 147/3 147/6 147/12 147/14 148/7 148/20 149/1 149/3 150/7 151/21 152/19 159/11 161/3 164/9 171/7 171/18 171/23
informed [11] 97/22 120/8 122/15 122/18 123/4 123/9 139/7 152/14 164/7 171/17 171/24
infrequently [4] 90/23 96/15 115/3 168/11
infused [1] 53/15
Ingram [3] 33/15 33/16 55/22
inherited [1] 148/11
inhibitors [1] 53/5
initial [1] 133/23
injecting [1] 88/17
injury [1] 140/11
Inman [1] 138/17
inoculation [1] 102/3
inquest [1] 127/9
inquests [1] 124/1
Inquiry [7] 1/22 110/9 132/25 138/3 148/24 149/7 168/4
Inquiry's [1] 151/18
insight [6] 24/2 31/10 36/19 61/11 65/5 68/8
insists [1] 64/25
insofar [2] 26/1 63/7
insoluble [1] 36/3
Institute [2] 16/18 31/3
institution [1] 60/7
instructed [1] 43/11
instructions [1] 124/18
instructive [2] 24/1 137/7
instrumental [1] 71/18
insufficient [3] 72/7 72/12 77/6
intended [3] 97/21 123/21 134/19
intending [1] 35/11
intention [3] 25/19 92/11 107/19
interactions [1] 42/3
interested [3] 48/18 64/12 64/13
interesting [4] 83/3 136/2 136/14 148/19
interests [1] 97/3
interim [2] 55/10 116/3
intermittent [1] 54/22
internal [2] 19/3 45/1
International [2] 3/23 3/25
interpretation [1] 71/3
interpreting [1] 161/12
intervals [2] 27/13 109/25
into [20] 3/4 24/2 30/19 31/11 51/5 54/23 55/15 61/11 65/5 78/8 88/17 119/19 126/10 126/13 141/10 146/14 146/20 153/16 157/6 159/19
intolerable [1] 21/13
intravenous [1] 157/16
introduce [2] 88/10 113/10
introduced [5] 13/2 13/14 14/20 15/6 109/17
introduction [8] 7/23 13/24 21/1 44/10 63/1 87/2 89/12 115/20
invariable [1] 60/3
invested [1] 139/1
investigate [1] 125/7
investigation [6] 1/22 85/11 99/7 124/10 126/22 126/23
invitation [4] 77/14 94/15 126/25 127/17
invited [4] 27/14 75/7 105/25 118/21
inviting [1] 99/15
involved [10] 5/24 50/13 60/16 62/1 64/13 66/14 73/13 152/12 153/20 156/19
involvement [1] 83/24
involves [1] 27/12
involving [3] 42/23 101/3 102/12
irresponsible [1] 92/24

F:

I

isn't [1] 3/10
isolation [1] 161/10
issue [34] 25/22 29/14 30/11 42/5 42/22 48/3 54/10 59/10 61/6 64/7 65/10 75/10 86/7 86/20 90/4 90/8 122/7 122/16 123/9 124/9 130/12 130/13 131/12 138/12 140/20 142/22 147/19 147/23 149/3 153/9 154/22 155/1 161/17 172/1
issued [9] 26/12 34/3 34/8 113/24 114/2 114/3 124/17 127/1 163/1
issues [10] 22/12 27/17 37/16 61/20 123/17 141/1 141/8 141/21 164/11 170/7
it's [101] 4/4 6/23 7/14 11/15 15/21 16/9 24/1 26/9 26/13 30/5 30/17 32/24 33/19 34/1 36/9 36/16 38/5 43/2 45/19 48/13 49/9 49/24 50/25 51/1 58/16 58/17 60/7 64/3 65/15 66/15 67/10 68/14 69/2 69/23 70/23 71/5 71/12 71/12 72/11 73/6 73/14 74/1 74/6 76/3 77/3 77/14 79/7 79/7 80/8 83/2 84/22 92/4 93/19 94/24 95/5 95/5 96/23 96/23 97/16 97/20 98/6 100/8 100/9 106/25 107/1 109/15 109/20 109/21 111/5 111/9 116/2 116/19 116/19 118/9 119/6 120/25 122/1 122/10 122/17 124/11 132/11 132/14 133/22 137/7 138/15 140/20 141/23 142/24 145/5 145/6 145/12 145/12 147/8 148/9 148/10 148/14 149/15 149/18 153/16 161/7 161/16
It's declining [1] 77/14
its [38] 1/10 3/5 3/6 4/10 6/5 6/6 9/17 15/10 15/11 19/21 20/3 24/8 29/6 45/18 54/21 55/14 58/9 61/16 63/17 67/20 92/1 92/5 103/15 107/6 117/21 121/3 141/21 143/4 143/11 149/8 150/4 156/16 159/12 166/13 167/3 167/21 170/18 170/24
itself [4] 4/17 45/17 141/20 169/25
IX [18] 3/15 3/25 6/20 12/2 15/9 39/8 50/17 80/21 87/3 88/11 98/19 100/12 101/7 101/19 111/1 112/2 112/15 142/7
IX ... both [1] 39/8

J

James [4] 5/9 5/12 31/7 31/12
Jane [1] 158/16
January [19] 34/2 65/14 65/17 67/17 68/1 68/3 87/25 88/1 90/3 90/7 109/21 110/6 118/10 121/25 122/7 123/6 123/9 158/17 169/12
January 1983 [1] 90/3
January 1985 [1] 169/12
January 1988 [3] 122/7 123/6 123/9
jaundice [4] 60/13 60/18 60/19 155/14
Jean [1] 31/20
Jenkin [1] 58/19
Jersey [1] 34/12
JEVA0000006 [1] 148/7
Joan [1] 5/15
John [5] 5/17 90/14 131/18 135/7 146/24
Johnson [1] 139/6
Johnson's [1] 138/21
joint [1] 81/18
jointly [1] 72/24
joints [1] 140/13
Jones [1] 107/3
journal [8] 66/24 67/10 67/19 110/24 158/2 158/17 160/2 161/7
joy [1] 19/14
judged [1] 87/12
judgment [1] 115/10
Judith [1] 7/15
July [22] 16/8 18/12 22/15 24/3 24/5 25/18 74/1 74/14 76/12 76/14 76/23 77/5 77/12 79/5 83/17 113/16 117/7 127/24 128/22 129/9 131/17 133/13
July 13th [1] 74/14
July 1972 [1] 18/12
July 1977 [1] 25/18
July 1991 [1] 133/13
June [14] 7/1 33/11 34/2 72/20 72/22 110/22 113/13 114/20 114/22 115/15 129/12 130/9 130/11 130/23
June 1970 [1] 7/1
June 1985 [3] 114/20 114/22 115/15
June 1989 [1] 130/9
June 1991 [1] 130/11
June, [1] 37/1
June, 1980 [1] 37/1
Juniper [1] 138/18
just [63] 3/9 8/13 13/16 15/18 15/20 16/2 26/8 27/8 31/10 32/3 33/25 34/23 36/12 36/19 42/2 46/15 47/20 48/5 48/6 48/23 53/10 54/1 55/1 58/10 58/16 64/18 68/15 71/22 72/15 72/21 75/16 76/7 77/8 77/21 83/23 86/7 86/25 88/5 92/5 100/2 100/8 100/14 105/6 112/5 117/9 128/25 136/18 136/24 137/6 138/11 140/25 142/22 144/21 148/6 149/15 150/4 151/11 151/16 156/13 159/25 162/3 169/3 172/24
justification [1] 92/1
justified [4] 91/13 91/24 113/6 138/23
justify [2] 21/21 163/22

K

Kaposi's [1] 66/8
Katharine [1] 32/17
Katharine Dormandy [1] 32/17
keen [3] 67/2 91/15 131/9
keep [3] 23/4 23/5 137/21
kept [5] 29/10 78/4 78/16 146/21 146/25
Kernoff's [1] 66/1
key [9] 3/18 4/25 6/1 31/23 106/16 146/16 151/2 169/23 170/12
key-to-disc [1] 146/16
Keying [1] 146/14
Keying-in [1] 146/14
kind [5] 67/8 91/2 134/25 142/8 145/25
Kingdom [5] 9/4 17/4 35/13 87/8 154/2
knew [2] 63/9 67/18
know [45] 1/15 22/9 22/19 27/7 33/5 33/23 35/3 40/18 41/16 58/8 60/23 61/25 63/11 65/13 68/5 71/12 71/20 72/4 72/10 74/18 75/8 79/21 83/25 85/22 89/22 98/25 108/6 109/18 110/5 110/22 128/3 128/19 130/17 130/20 131/2 131/6 131/8 131/13 132/12 132/21 134/4 137/25 141/2 151/5 160/4
knowledge [15] 3/2 59/25 61/15 63/7 64/1 68/9 76/16 86/13 126/16 152/8 152/14 157/11 167/21 170/15 170/17
known [14] 10/18 77/4 79/6 84/13 95/12 98/24 121/15 127/21 134/15 151/17 156/7 156/22 157/7 164/15
Koate [3] 34/20 35/1 35/22
Kryobulin [5] 18/15 18/20 34/18 36/2 75/1

L

lab [4] 128/13 135/6 135/10 136/7
label [1] 161/14
laboratories [7] 17/8 35/22 44/12 44/13 55/16 59/6 159/19
laboratory [13] 2/8 2/9 5/3 6/12 9/18 12/24 25/8 82/5 92/25 98/9 102/6 144/6 144/20
lack [5] 23/22 40/22 86/14 139/15 167/21
Lancet [4] 55/20 55/25 162/10 163/14
Lane [4] 86/18 87/6 87/11 87/19
Lane's [2] 86/22 87/15
large [18] 2/13 40/5 41/3 47/14 51/18 51/21 57/17 58/25 62/18 69/11 88/25 93/4 154/11 154/19 159/4 166/24 167/1 167/16
larger [3] 37/15 46/19 101/13
largest [4] 2/10 34/4 45/23 69/8
last [23] 11/23 11/24 17/1 23/12 25/10 37/17 54/11 64/15 70/17 72/10 72/11 75/17 81/20 82/6 82/20 83/2 83/9 103/4 108/10 119/2 119/4 157/12 165/6
last ... was [1] 165/6
late [8] 1/6 9/14 60/11 106/15 127/20 141/19 153/6 155/18
later [18] 5/7 15/13 30/25 31/2 49/1 52/15 53/1 54/23 61/2 63/20 85/19 90/11 101/24 105/8 106/10 116/11 147/16 172/4
latest [1] 169/11
latter [2] 104/23 114/12
LAV [1] 161/14
Lawrence [1] 66/2
lead [1] 25/14
leadership [1] 4/20
leading [1] 3/3
leads [1] 42/22
learn [1] 137/8
learnt [1] 2/1
least [22] 20/24 22/11 22/12 25/19 36/21 47/19 69/16 73/2 77/4 87/15 87/24 88/9 93/12 103/20 110/6 111/2 123/9 138/5 158/6 160/3 160/10 167/20
leave [3] 58/10 61/7 75/16
leaving [2] 1/12 119/9
Lechner [2] 74/24 75/19
led [1] 145/7
Lee [12] 32/4 32/13 32/14 80/3 80/11 81/6 81/15 81/16 82/14 83/13 83/22 172/17
left [2] 20/9 163/21
legal [2] 122/22 170/6
legitimate [1] 23/21
less [13] 13/19 20/15 20/19 21/17 41/6 51/20 71/9 97/8 114/16 154/17 166/6 166/6 166/21
let [4] 48/23 74/18 75/7 89/22
letter [91] 16/7 21/9 21/10 22/14 24/4 33/13 34/11 34/25 35/3 36/15 36/17 36/22 38/3 38/13 41/21 42/15 43/1 44/24 55/20 55/23 55/24 57/15 58/17 64/4 64/5 68/11 72/18 72/22 73/3 73/7 73/25 74/1 76/5 77/11 78/13 80/4 80/5 80/8 81/15 82/16 83/6 85/3 86/18 87/22 87/23 90/15 92/5 92/7 93/6 93/11 93/12 93/19 102/18 103/10 104/7 106/22 107/21 109/11 109/19 109/21 110/23 111/8 112/5 113/15 113/18 124/8 124/11 129/12 130/11 131/17 132/11 132/15 133/24 135/6 135/10 136/1 136/6 136/7 136/8 136/10 136/11 137/6 138/13 138/18 138/20 139/18 141/25 142/18 142/21 162/10 164/3
letters [2] 22/6 57/23
level [4] 32/2 50/12 155/22 155/23
levels [2] 23/17 24/13
LFTs [1] 104/25
liberty [1] 43/6
licence [2] 87/10 87/11
licences [1] 46/5
licensed [2] 18/15 56/9
licensing [2] 18/19 92/18
lies [2] 23/18 56/22
life [4] 39/12 103/16 165/13 167/22
lifted [1] 109/16
lifting [1] 109/13
light [2] 25/4 83/21
like [5] 24/19 38/25 61/24 103/13 107/14
likelihood [1] 54/22
likely [20] 13/22 22/10 29/16 29/22 29/24 50/4 54/8 62/22 71/5 75/22 93/19 94/1 102/7 106/3 107/17 124/22 132/2 132/5 151/1 154/18
limit [2] 20/17 20/22
limitation [1] 56/7

L

limited [6] 32/2 93/20 122/4 126/24 154/17 159/11
limiting [2] 44/8 155/16
line [1] 52/11
lines [17] 24/10 27/4 49/25 50/6 51/5 52/23 72/11 73/14 88/6 89/3 97/10 104/6 126/4 147/11 157/12 168/15 169/15
link [1] 78/20
linked [1] 110/14
liquid [1] 32/10
list [8] 3/10 3/11 21/19 46/2 105/25 121/25 135/13 151/16
listed [1] 149/10
listening [2] 6/8 33/15
Lister [1] 16/18
Lister Institute [1] 16/18
litigation [14] 4/5 6/2 6/3 6/10 61/12 61/15 65/11 85/20 86/1 109/4 138/10 153/14 153/25 155/10
litres [1] 11/2
little [16] 7/11 10/13 30/23 35/19 43/10 55/15 61/3 100/14 111/7 129/10 134/15 138/9 156/22 156/25 158/24 160/7
lived [1] 62/19
liver [23] 5/18 5/22 5/25 61/22 61/23 98/2 99/3 99/6 99/7 99/7 132/3 134/8 134/9 134/11 134/13 136/21 155/21 155/22 155/25 156/1 156/2 156/3 157/4
local [4] 96/13 99/6 140/20 159/16
locally [3] 25/10 107/24 112/2
located [1] 94/13
location [1] 9/17
lockable [1] 146/12
locked [4] 57/18 146/12 146/21 147/1
London [2] 68/3 160/6
long [16] 26/20 30/8 39/14 51/10 56/4 57/12 61/10 68/6 134/10 137/13 146/8 150/22 153/16 155/13 157/1 159/12
long-drawn [1] 39/14
long-term [3] 30/8 61/10 134/10
longer [3] 112/25 113/4 137/21
look [47] 4/12 7/14 9/24 13/16 16/6 24/1 27/16 27/17 28/17 33/25 42/2 44/25 45/14 46/12 46/15 49/1 49/11 49/13 54/23 58/16 62/6 65/15 71/22 76/11 77/12 78/18 80/5 80/19 81/7 82/8 82/16 84/2 85/19 86/6 86/7 86/11 86/24 94/19 94/24 100/2 103/13 122/19 128/21 136/20 153/13 156/10 172/23
looked [31] 18/23 36/24 42/16 43/9 55/21 61/7 62/9 63/14 65/2 65/8 68/1 69/20 71/21 72/20 73/5 77/8 79/4 87/24 88/1 92/5 105/6 110/17 117/9 123/6 128/25 132/15 142/13 151/3 158/18 160/5 168/8
looking [17] 1/6 6/11 10/5 14/25 42/15 54/2 61/20 80/3 80/14 85/2 99/24 100/9 101/13 122/2 130/12 147/13 149/4
looks [4] 9/22 49/1 65/10 129/3
Lord [4] 27/1 42/7 45/15 48/4
Lord Owen [3] 42/7 45/15 48/4
lot [2] 141/6 147/9
low [3] 80/15 82/19 155/15
lower [2] 35/21 67/12
Ltd [1] 35/22
luck [1] 19/13
lunch [2] 94/23 99/19
Luncheon [1] 99/22

M

Macfarlane [2] 4/21 8/11
made [61] 6/18 9/5 9/18 10/14 10/23 12/9 15/7 19/19 21/2 21/25 25/10 26/12 28/8 32/9 34/18 34/18 34/19 34/19 34/20 35/1 35/5 38/20 40/2 41/1 41/4 43/20 43/23 44/21 51/7 52/13 53/13 53/19 55/9 55/11 55/18 57/3 57/6 60/19 62/18 63/21 77/24 95/14 96/12 98/10 101/1 101/23 105/17 106/17 112/4 117/17 125/5 135/16 138/25 139/14 154/19 155/8 158/24 160/7 163/16 164/8 165/20
Mail [1] 82/13
main [5] 30/6 31/17 67/11 80/14 142/1
mainly [5] 8/2 16/20 39/3 42/4 111/21
maintaining [1] 7/20
major [5] 7/20 8/3 18/10 50/13 89/13
make [22] 8/14 12/16 12/17 12/20 12/25 20/6 30/2 32/8 34/23 40/18 40/21 54/4 56/7 76/25 82/11 92/19 103/16 113/7 114/14 128/8 128/17 154/24
makes [4] 3/6 39/12 142/18 157/25
making [7] 29/16 52/3 55/17 57/24 73/3 79/24 90/17
male [1] 150/14
man [1] 110/11
manage [2] 21/17 82/11
managed [3] 91/5 167/8 171/20
management [5] 6/23 8/17 8/25 133/8 143/4
Manchester [3] 146/24 146/25 158/10
manifest [1] 155/14
manipulation [1] 51/19
manner [3] 91/8 92/22 152/15
Mannucci [1] 156/4
manually [1] 143/7
manufacture [3] 6/19 41/7 51/14
manufactured [5] 30/13 47/16 105/3 105/7 105/10
manufacturers [4] 58/23 84/20 88/18 112/18
manufacturing [1] 89/8
many [13] 26/10 30/12 31/25 32/11 39/12 39/15 39/15 44/20 52/16 69/12 112/11 131/21 138/2
March [13] 18/20 27/18 45/20 90/13 92/4 92/8 93/8 93/10 102/18 103/21 104/1 139/19 140/3
March, [1] 37/3
March, 1981 [1] 37/3
marked [5] 144/23 145/5 145/7 145/9 145/12
market [6] 40/9 94/2 94/5 105/22 108/18 108/19
marketed [1] 128/1
marking [1] 145/2
Mary [2] 5/11 136/19
match [1] 119/14
material [78] 10/2 10/17 10/21 11/6 12/11 12/13 14/12 15/3 15/15 16/19 16/23 17/5 17/6 17/10 17/24 17/25 18/4 18/8 18/9 20/14 20/16 21/22 22/1 24/6 26/14 27/20 27/22 27/25 28/2 28/4 28/7 29/10 29/13 29/22 29/23 30/2 31/18 32/2 32/9 32/12 33/2 33/20 39/24 39/25 40/8 40/20 40/21 43/22 43/23 44/2 48/17 54/1 54/14 56/12 57/20 61/17 62/17 63/25 77/7 84/21 91/14 91/16 91/25 92/21 107/16 107/24 108/15 112/17 114/2 114/3 114/9 114/17 114/21 115/2 115/12 127/6 156/6 159/17
materials [20] 7/3 7/5 10/3 10/10 12/3 30/24 35/15 41/19 43/14 43/16 44/8 50/3 57/18 59/24 72/23 87/18 113/1 143/18 156/21 166/2
matter [14] 23/11 63/11 65/8 70/7 118/3 120/9 124/3 139/9 146/1 153/12 158/6 158/9 158/13 168/7
matters [12] 1/10 1/20 22/13 33/14 74/16 75/8 78/12 79/24 83/25 95/7 121/20 133/20
Matthews [8] 5/9 5/20 26/3 28/22 31/7 31/12 32/7 84/4
Matthews' [1] 32/22
maximal [1] 23/4
may [72] 1/16 9/10 9/11 9/11 34/11 38/10 42/19 47/11 49/2 49/11 51/20 52/7 54/5 55/4 58/11 66/25 68/10 68/12 71/18 71/20 73/5 73/7 73/9 73/21 76/15 79/6 79/17 80/3 82/19 87/7 88/16 91/10 94/8 94/18 96/21 103/11 108/19 110/14 111/2 112/9 112/13 113/1 113/8 114/4 116/24 118/3 123/5 127/5 131/8 134/19 136/15 137/6 137/7 137/15 140/8 140/25 145/10 147/22 149/1 156/5 158/10 160/8 160/24 161/7 161/17 164/18 165/7 168/24 169/9 170/7 170/13 172/24
May 1977 [1] 34/11
maybe [1] 87/25
Maycock [7] 21/8 21/9 22/3 26/11 28/3 46/10 62/25
Maycock's [2] 20/7 45/6
Mayor [1] 27/1
me [14] 21/20 22/8 40/20 48/23 64/15 74/18 90/19 114/13 124/22 124/23 130/20 131/21 137/11 172/16
mean [5] 2/15 2/17 71/1 94/8 131/25
means [3] 27/10 96/8 131/9
meant [4] 70/16 82/15 83/14 167/4
meantime [1] 114/8
measure [1] 55/10
medical [15] 3/11 3/13 4/2 43/4 44/25 49/7 68/13 68/21 110/24 129/13 137/2 137/5 149/20 150/25 153/3
Medicine [5] 66/24 67/10 67/19 74/13 158/17
Medicines [1] 75/10
meet [3] 15/11 41/13 148/1
meeting [47] 16/12 25/25 38/20 38/21 40/1 42/19 43/9 45/10 45/18 45/20 63/13 63/15 63/20 64/18 64/21 65/13 67/18 68/2 68/4 71/19 71/24 71/25 72/11 75/3 77/4 77/19 84/2 85/22 85/23 86/19 86/23 87/16 90/6 106/9 106/16 107/1 107/4 107/9 121/24 122/7 133/4 151/6 151/7 151/9 151/9 160/6 172/11
meetings [7] 60/3 60/4 61/8 63/24 64/3 158/8 160/5
meets [1] 58/3
member [8] 3/16 3/24 4/3 4/6 4/11 146/9 150/23 150/24
members [2] 123/2 150/1
membership [1] 149/19
memo [1] 108/4
memorandum [2] 103/22 143/10
men [3] 120/16 120/18 150/11
mention [2] 39/1 151/16
mentioned [5] 114/9 131/20 146/22 149/9 149/12
mentions [1] 55/19
merely [1] 26/15
merits [1] 46/13
method [4] 49/18 70/23 104/13 131/5
methods [7] 88/15 89/8 96/11 96/24 102/2 131/3 132/6
microfilmed [2] 137/10 137/18
mid [5] 61/25 80/2 131/12 147/20 155/11
mid-1970s [1] 155/11
mid-1980s [1] 147/20
mid-1983 [1] 80/2
mid-70s [1] 61/25
mid-991 [1] 131/12
middle [2] 113/22 115/18
might [20] 41/12 53/1 53/10 53/18 66/11 68/23 70/16 70/22 78/19 89/16 92/16 99/16 106/1 119/13 128/14 134/25 144/22 161/10 166/8 167/8
mild [3] 100/20 155/15 156/25

F:

M

mildly [9] 14/10 72/14 90/21 91/10 91/20 91/23 92/9 162/22 168/12
million [4] 40/7 56/15 57/7 167/2
mind [4] 39/6 45/10 49/10 140/16
minimise [1] 125/21
minimum [2] 20/11 39/20
ministry [3] 21/16 30/16 38/23
minute [2] 45/2 45/6
minutes [10] 45/18 49/6 49/11 68/2 71/23 71/25 84/7 121/24 133/11 160/5
misdated [2] 136/1 136/10
Miss [1] 65/19
Miss Spooner [1] 65/19
mistake [1] 135/8
mix [1] 69/18
ml [1] 11/4
MMWR [3] 158/2 158/11 161/20
model [2] 135/2 135/3
modes [1] 27/10
modify [2] 167/22 168/1
moment [12] 8/5 10/9 48/6 53/6 73/20 76/7 80/5 99/19 110/20 135/9 144/21 147/24
moments [1] 132/15
Monday [1] 74/18
money [10] 19/2 21/4 24/15 28/1 55/15 57/7 57/9 59/13 138/24 139/3
monitored [1] 104/25
monitoring [2] 60/13 61/22
month [6] 25/12 34/8 63/21 66/19 108/19 131/16
monthly [1] 109/25
months [7] 16/11 96/18 97/6 100/8 129/22 129/23 164/5
moot [1] 167/11
morale [1] 108/25
more [53] 10/20 11/5 12/13 13/8 14/10 20/16 20/19 21/4 21/5 21/18 21/19 23/2 27/17 27/17 28/17 29/18 30/8 30/23 36/3 37/8 38/16 40/7 41/24 44/16 50/20 52/8 59/13 62/6 62/22 63/19 63/19 70/21 71/1 71/5 71/7 71/7 71/11 77/19 100/5 108/20 114/23 116/16 122/19 132/2 134/13 134/18 141/6 155/17 158/18 166/19 167/6 171/1 171/22
Moreover [1] 159/21
morning [4] 43/10 79/13 138/17 141/5
mortality [1] 68/5
Mortimer [1] 128/2
most [24] 5/8 7/17 14/1 14/1 18/9 37/13 43/16 88/22 100/20 109/9 111/15 114/13 117/4 118/16 128/12 132/3 134/12 136/14 140/12 155/16 158/1 158/3 165/16 166/25
mother [1] 110/12
mount [1] 108/25
mouse [1] 163/15
mouth [1] 126/13
move [5] 108/16 110/4 138/10 161/5 163/22
moving [2] 137/1 137/4
Mr [5] 16/9 107/3 125/24 138/17 138/18
Mr Inman [1] 138/17
Mr Jones [1] 107/3
Mr Juniper [1] 138/18
Mr Trillwood [1] 16/9
MRC [3] 4/11 130/5 149/19
MRC's [1] 49/16
Mrs [6] 5/11 65/20 95/16 136/15 146/8 146/17
Mrs Fletcher [2] 65/20 95/16
Mrs Mary [1] 5/11
Mrs Patricia [1] 146/8
Mrs Wallace [1] 146/17
Mrs X [1] 136/15
MS [14] 1/3 5/4 86/5 116/2 116/18 118/10 121/4 146/7 146/17 146/23 147/7 172/9 173/2 174/2
MS RICHARDS [4] 1/3 172/9 173/2 174/2
Ms Rosemary Spooner [1] 5/4
Ms Spooner [8] 86/5 116/2 116/18 118/10 121/4 146/7 146/23 147/7
much [22] 10/15 13/14 13/19 14/4 19/13 23/10 25/9 31/2 37/22 41/9 47/7 47/16 49/2 51/20 52/4 55/17 64/23 92/7 93/2 106/18 140/18 172/9
multi [1] 94/4
multi-centre [1] 94/4
multiple [2] 72/20 171/22
multiplicity [1] 49/9
must [7] 9/5 45/3 63/11 76/5 108/7 112/16 169/17
my [19] 18/18 19/5 22/5 36/2 37/19 43/6 48/6 56/7 74/17 110/8 114/11 115/12 124/15 125/16 125/21 125/24 131/19 137/20 173/2

N

name [8] 119/13 142/4 143/23 144/1 144/2 144/5 144/13 144/16
named [8] 87/8 87/21 89/15 117/22 119/19 147/6 147/12 153/20
names [12] 5/1 117/1 117/20 118/3 118/13 119/9 119/14 127/3 143/20 145/4 150/1 151/16
narrative [1] 156/15
nasty [1] 83/11
national [8] 4/7 38/16 62/24 90/10 102/17 122/21 144/17 147/18
nationally [1] 41/17
natural [2] 125/12 150/8
nature [3] 63/6 156/8 163/4
nausea [1] 130/2
near [2] 92/15 106/4
nearly [2] 12/11 25/9
necessarily [4] 3/10 51/11 109/3 132/14
necessary [7] 58/6 70/8 89/25 90/22 92/16 92/20 145/23
necessities [1] 57/10
need [25] 12/18 14/1 23/13 29/22 41/13 42/18 44/18 45/14 46/11 57/19 58/19 58/24 59/22 71/7 76/11 76/24 78/18 87/17 113/1 113/10 126/22 135/9 155/1 166/16 168/7
need' [1] 68/16
needed [8] 10/21 28/8 29/17 29/19 41/12 50/4 87/10 134/11
needing [1] 123/8
needs [6] 16/13 17/21 18/4 20/15 23/22 169/25
negative [8] 119/5 120/14 120/15 120/18 120/19 123/19 135/22 136/18
negotiate [1] 35/21
neither [1] 18/14
neuropsychiatric [1] 123/17
neuropsychological [1] 123/21
never [1] 12/13
new [13] 21/1 40/1 41/9 66/24 67/10 67/19 92/8 97/11 110/1 118/19 143/25 158/16 160/2
New England [4] 66/24 67/10 67/19 160/2
news [2] 133/22 133/23
next [45] 8/7 8/12 11/19 13/5 22/24 24/10 27/18 29/12 32/21 35/24 37/18 40/4 46/4 47/1 49/22 50/15 51/1 52/10 62/7 66/22 68/8 70/9 74/18 85/12 85/21 86/7 87/5 89/11 94/2 95/9 99/10 112/6 122/23 135/23 136/6 137/3 139/19 146/3 149/15 157/9 158/15 165/11 167/11 169/15 172/11
NHS [74] 10/11 10/22 11/7 11/10 12/2 12/20 12/20 13/10 15/3 15/15 22/7 22/9 22/22 25/10 25/13 25/20 34/5 36/25 37/3 37/4 37/8 37/10 37/14 37/23 38/11 40/15 47/15 55/11 55/13 56/14 57/3 57/6 57/9 58/3 58/23 59/4 59/21 63/5 69/11 69/13 69/18 69/22 69/25 70/3 70/12 70/20 71/1 71/8 72/17 81/13 81/23 83/11 83/19 84/10 84/16 95/2 95/23 98/19 101/10 101/14 104/24 105/2 105/16 108/20 113/20 113/24 115/12 164/22 164/23 165/25 166/3 167/17 168/10 169/21
NHS concentrate [1] 15/15
nice [1] 80/19
nine [4] 96/3 101/3 120/11 168/15
no [58] 6/1 9/17 13/9 17/6 17/23 19/14 22/7 23/18 34/5 47/19 50/17 53/9 54/9 54/19 54/25 57/18 67/24 68/19 70/13 73/11 85/16 87/10 89/12 91/1 93/18 97/9 102/5 103/16 104/18 105/5 107/23 112/25 113/4 114/24 115/1 119/19 120/9 121/15 122/14 124/16 126/9 126/14 127/18 137/19 137/21 139/5 140/6 140/15 145/4 157/6 160/10 160/16 162/3 165/2 170/2 172/12 172/25 173/4
no-one [1] 57/18
non [60] 61/5 61/5 61/10 61/10 61/15 61/15 74/2 74/3 74/8 74/9 80/17 81/2 81/10 84/19 88/12 88/13 95/11 95/11 95/13 95/13 95/21 96/3 96/3 98/7 98/7 98/11 98/12 99/4 99/5 100/23 100/24 101/8 101/8 102/7 102/7 102/8 102/8 102/21 102/21 103/6 103/6 104/14 104/14 111/1 113/5 115/1 115/2 115/6 115/6 122/24 123/3 127/21 127/21 128/14 128/14 151/21 156/22 156/22 170/20 170/20
Non A [1] 115/1
Non B hepatitis [1] 115/2
non-A [23] 61/5 61/10 61/15 74/2 74/8 88/12 95/11 95/13 96/3 98/7 98/11 99/4 100/23 101/8 102/7 102/8 103/6 104/14 115/6 127/21 128/14 156/22 170/20
non-A/non-B [1] 102/21
non-B [24] 61/5 61/10 61/15 74/3 74/9 88/13 95/11 95/13 95/21 96/3 98/7 98/12 99/5 100/24 101/8 102/7 102/8 103/6 104/14 115/6 127/21 128/14 156/22 170/20
non-blood [1] 122/24
non-commercial [3] 80/17 81/2 81/10
non-donor [1] 123/3
non-haemophilia [1] 84/19
non-heat-treated [1] 113/5
non-receipt [1] 151/21
none [3] 66/4 159/2 160/16
nonetheless [1] 119/12
nor [2] 18/15 158/25
normal [6] 67/14 82/19 83/4 83/8 140/6 155/23
normally [1] 124/23
not [141] 1/13 2/20 4/4 5/15 6/6 8/25 11/15 16/8 20/21 20/22 21/1 21/13 23/3 23/13 24/12 24/14 24/20 24/25 26/13 27/13 29/3 29/9 33/19 34/25 35/1 37/21 38/9 38/12 39/16 39/17 40/1 41/2 47/7 47/8 47/13 48/9 48/16 49/12 51/11 53/7 54/14 54/20 55/12 59/12 61/8 69/15 69/23 70/14 73/14 73/17 73/22 73/23 77/21 77/23 80/22 82/10 84/22 88/25 91/7 91/13 92/3 92/19 92/20 94/17 95/20 96/16 96/21 99/8 104/16 105/23 109/15 111/6 113/23 115/2 115/8 116/9 117/13 117/15 117/16 119/13 119/24 122/4 123/2 124/4 124/20 125/2 125/8 125/10 126/10 126/13 127/5 127/14 127/17 128/7 128/20 129/8 130/4 130/20 132/7 132/11 132/14

N

not... [40] 133/25 134/16 135/17 135/18 137/14 137/16 138/19 140/14 141/8 141/10 142/5 142/6 143/20 145/8 145/12 146/18 146/20 147/1 151/15 152/18 153/23 154/21 155/12 157/3 159/6 159/7 160/13 161/2 161/4 162/1 167/9 167/15 167/20 167/25 167/25 168/1 172/1 172/2 172/10 172/24
note [7] 72/25 79/7 86/22 99/16 123/5 128/13 170/5
noted [7] 18/18 53/20 135/14 135/18 146/19 158/23 160/2
notes [1] 78/25
nothing [1] 124/24
notice [1] 59/9
notification [2] 143/25 144/10
notify [2] 93/22 144/11
November [7] 1/9 58/18 83/6 83/7 83/18 121/16 164/3
November 1982 [1] 164/3
November 1986 [1] 121/16
now [36] 3/10 10/13 12/16 17/7 17/24 19/6 20/7 20/18 25/9 25/11 27/3 46/5 49/13 56/9 56/10 58/16 59/8 68/1 68/4 74/1 75/4 87/22 99/17 106/18 111/3 111/15 119/6 127/1 127/21 127/25 128/23 131/22 134/1 137/5 151/17 169/1
Nuffield [1] 138/14
nuisance [1] 36/4
number [56] 2/13 2/20 3/7 6/13 13/21 14/21 16/24 21/24 25/23 26/4 28/25 29/20 42/2 48/8 49/16 49/19 50/23 50/25 54/3 55/2 60/24 63/14 68/2 71/21 72/1 86/4 89/1 91/3 93/20 94/6 95/7 97/14 110/25 112/12 117/23 119/10 120/25 124/21 144/16 144/17 149/6 149/10 149/21 150/1 151/24 152/11 152/21 153/9 153/18 153/21 154/17 155/19 156/2 162/5 163/6 170/7
numbers [6] 91/20 93/5 119/16 130/8 157/3 166/24
nurse [2] 5/11 136/20
nursing [1] 8/21

O

O'Callaghan [1] 139/20
o'clock [1] 99/20
object [2] 80/14 97/17
objection [1] 126/14
objective [1] 95/6
obligation [1] 125/6
obliged [1] 40/9
obscure [1] 158/2
observation [11] 8/14 26/8 37/9 38/19 55/18 61/23 62/14 75/12 76/25 78/24 157/25
observations [5] 9/10 15/24 25/2 75/6 101/16
observed [2] 78/7 79/8
observes [2] 20/25 57/25
obtain [7] 31/24 82/11 95/5 97/22 101/20 108/13 164/8
obtained [7] 97/19 98/10 108/10 119/1 120/4 122/15 123/4
obtaining [1] 153/8
obvious [1] 157/15
obviously [17] 1/18 2/4 2/25 17/18 26/4 27/16 34/12 38/10 48/3 73/10 82/14 83/13 118/3 149/9 158/18 165/19 172/20
occasion [2] 87/24 158/18
occasionally [1] 36/2
occasions [6] 29/1 63/15 68/2 71/22 72/21 135/17
occupied [3] 5/4 86/16 154/5
occupies [1] 2/18
occur [3] 14/12 134/8 134/17
occurrence [3] 97/12 106/12 148/11
occurs [4] 27/12 27/14 109/5 134/13
October [17] 1/1 19/6 19/22 26/1 30/23 43/10 64/2 65/6 77/15 81/16 83/18 116/19 120/24 135/24 139/9 151/6 173/8
October 1972 [2] 30/23 43/10
October 1973 [2] 19/6 19/22
October 1982 [1] 65/6
October 1990 [1] 135/24
October/November [1] 83/18
odd [1] 21/15
off [2] 54/24 94/17
offer [1] 131/10
offered [2] 29/24 87/11
office [2] 146/10 146/11
officer [4] 43/4 44/25 68/13 129/13
offload [1] 108/17
offshoots [1] 149/21
often [3] 8/25 17/20 23/21
oh [3] 8/7 38/15 134/1
old [3] 66/19 110/11 137/21
omitting [1] 119/8
once [4] 22/16 91/7 142/8 170/9
one [70] 2/19 6/1 10/17 15/24 17/8 17/11 17/21 20/8 30/6 31/17 32/17 33/25 38/10 43/22 44/2 49/19 52/4 55/2 56/14 57/18 59/18 60/17 61/9 64/20 64/23 66/6 70/7 70/22 76/18 76/22 76/24 78/5 78/12 78/25 78/25 79/14 79/21 82/16 87/24 93/21 98/22 99/4 102/25 104/11 105/2 110/11 111/2 114/11 126/4 129/22 131/3 135/19 135/21 135/25 137/9 138/20 141/12 141/13 142/22 147/20 148/19 149/12 150/23 153/3 153/4 158/7 158/18 161/16 164/12 171/22
one's [1] 49/10
one-tenth [1] 44/2
ones [2] 135/15 135/16
ongoing [3] 61/22 83/16 128/6
only [39] 7/24 20/10 21/15 23/3 26/11 26/25 44/1 55/14 65/2 69/13 69/13 69/25 69/25 78/5 81/13 86/22 91/11 93/4 93/20 95/12 100/22 102/1 102/9 104/11 108/10 111/25 112/2 112/14 115/3 124/21 128/10 130/2 130/5 139/1 144/25 146/22 147/7 147/12 153/7
onto [2] 108/17 110/4
onwards [3] 114/20 115/16 141/19
opening [1] 124/11
operate [1] 116/9
operation [3] 12/22 17/11 21/19
operations [1] 24/19
operative [1] 95/19
opinion [4] 22/5 59/3 138/21 169/20
opportunity [4] 38/25 70/11 76/19 76/20
opposed [1] 81/13
Option [1] 165/23
options [4] 164/20 165/3 165/4 165/5
or [143] 1/13 1/24 1/24 3/9 3/19 3/20 3/21 5/8 5/8 6/16 8/2 9/4 11/17 19/7 20/19 21/4 23/14 24/7 24/18 27/8 27/11 27/13 30/16 31/14 36/5 40/4 42/21 44/14 45/24 48/10 48/24 49/19 51/4 52/21 54/7 55/15 57/3 60/7 61/9 61/9 63/9 64/20 66/10 66/18 69/24 70/24 71/2 71/2 71/7 72/15 72/16 75/25 76/4 76/15 76/16 76/19 76/23 79/21 80/24 81/4 84/10 85/3 86/14 86/21 87/9 90/23 93/1 94/8 95/19 95/23 97/19 98/7 99/5 100/12 101/7 102/4 103/19 104/10 108/19 110/3 113/5 115/3 115/8 115/18 118/1 123/10 124/25 128/9 128/13 130/1 134/23 135/25 137/12 137/15 137/19 138/4 139/8 139/16 140/11 141/8 141/8 142/5 142/6 142/7 144/16 148/25 149/11 150/6 151/14 151/15 151/21 152/6 152/8 152/12 152/13 152/16 152/17 152/19 152/19 153/8 153/10 154/17 156/7 156/8 161/1 161/3 162/1 162/23 163/11 164/22 165/3 165/21 165/24 167/6 167/9 168/11 168/12 171/5 171/20 171/22 172/2 172/5 173/5
oral [3] 1/12 132/22 153/4
orally [1] 42/7
order [10] 20/12 29/24 57/8 80/4 80/20 90/2 97/22 107/15 109/25 114/4
ordinary [4] 52/7 110/10 113/9 140/22
ordinate [2] 94/16 150/17
ordinated [4] 51/21 77/18 105/23 143/5
ordinating [1] 79/24
organisation [5] 20/7 40/22 51/25 154/1 156/17
organisations [1] 153/19
organise [2] 26/24 27/3
origin [1] 75/1
original [3] 55/24 137/14 137/16
Ortho [1] 128/1
Orthopaedic [1] 138/14
other [70] 2/22 3/15 4/25 6/14 9/20 12/6 13/13 17/4 17/8 17/13 18/9 18/21 23/15 24/19 24/22 30/8 33/23 47/23 57/9 62/20 63/25 66/5 66/10 67/18 67/24 70/23 72/13 74/11 74/22 76/21 76/23 78/9 79/20 81/13 84/22 86/3 86/15 88/1 88/14 91/9 91/17 94/9 95/19 97/5 101/17 108/15 110/8 110/12 112/22 113/5 115/23 124/21 126/9 126/11 130/4 131/21 133/1 137/15 138/1 139/5 139/13 141/18 144/7 145/3 145/8 145/22 149/5 157/14 162/18 165/3
others [12] 8/11 19/19 21/25 23/18 26/4 36/3 39/15 49/16 69/13 76/9 77/9 95/16
otherwise [1] 41/15
ought [1] 86/10
our [46] 16/13 17/25 20/13 20/15 20/17 20/18 20/22 21/18 25/12 25/14 34/22 34/25 36/1 36/25 39/19 40/10 40/21 64/14 64/17 69/12 80/20 81/3 81/18 82/22 91/11 92/8 92/11 103/6 103/14 107/15 111/12 128/4 128/10 128/25 129/1 131/4 131/20 131/21 132/6 132/17 136/13 136/14 136/21 137/9 140/2 140/12
ourselves [1] 137/23
out [78] 2/1 8/13 8/14 10/8 10/10 11/22 12/1 19/12 31/24 34/22 35/1 38/9 41/12 45/15 46/2 53/2 60/9 63/19 70/2 72/19 72/23 73/3 78/4 80/12 81/5 81/18 82/2 82/4 82/10 82/19 83/12 88/3 88/20 89/3 89/7 89/19 90/3 92/14 92/17 93/11 93/12 94/19 95/12 96/15 99/8 99/14 101/5 101/6 104/2 106/5 113/19 114/19 115/5 115/21 117/20 121/11 123/20 123/23 127/5 127/11 130/25 133/5 133/20 134/24 142/10 142/15 144/22 146/10 146/15 148/10 156/15 157/1 163/12 164/19 165/4 166/11 169/8 170/1
outcome [1] 134/12
outlined [4] 28/22 40/3 96/11 97/15
output [1] 58/3
outset [1] 141/5
outside [1] 2/13
over [43] 1/9 4/24 6/13 7/11 11/15 12/8 12/18 13/5 14/9 23/6 25/2 26/6 26/16 27/18 28/18 30/4 36/25 46/11 48/7 51/24 53/24 56/15 57/3 59/2 74/20 82/5 85/1 85/12

F:

O

over... [15] 86/22 87/13 89/20 91/6 97/24 111/17 116/16 120/1 123/1 125/22 128/11 130/15 141/4 147/2 170/17
overall [1] 11/17
overleaf [2] 48/10 48/11
overseas [2] 30/14 46/7
overt [1] 155/14
overview [3] 11/14 142/12 154/2
Owen [4] 41/20 42/7 45/15 48/4
own [9] 4/5 34/25 40/21 55/14 65/7 91/20 118/1 124/15 165/5
Oxford [186]
Oxford's [7] 1/21 2/3 33/8 36/12 38/4 41/17 141/13
Oxford-related [1] 152/4
Oxfordshire [4] 106/23 122/3 123/8 138/15
OXUH0000004 [1] 72/22
OXUH0000422 [1] 109/20
OXUH0000644 [1] 19/5
OXUH0000649 [1] 22/4
OXUH0000663 [1] 19/24
OXUH0000673 [1] 16/7
OXUH0000676 [1] 103/10
OXUH0000679 [2] 102/15 103/2
OXUH0000725 [1] 127/23
OXUH0000917 [1] 33/10
OXUH0001158 [1] 137/2
OXUH0001219 [1] 118/6
OXUH0001262 [1] 124/7
OXUH0001293 [1] 138/13
OXUH0001299 [1] 129/12
OXUH0001374 [1] 139/18
OXUH0001534 [1] 141/23
OXUH0001612 [1] 73/25
OXUH0001617 [1] 64/1
OXUH0001860 [2] 135/5 136/6
OXUH0001861 [1] 128/21
OXUH0001862 [2] 133/3 133/12
OXUH0001863 [2] 130/10 130/22
OXUH0001864 [1] 131/16
OXUH0002245 [1] 68/11
OXUH0002246 [2] 71/17 77/12
OXUH0002251 [1] 120/23
OXUH0002260 [1] 121/22
OXUH0002971 [2] 80/4 83/5
OXUH0002972 [1] 81/16
OXUH0002974 [1] 82/17
OXUH0002977 [1] 83/2
OXUH0003728 [1] 25/24
OXUH0003761 [6] 22/14 24/2 34/10 106/25 107/22 108/3
OXUH0003771 [1] 113/14
OXUH0003775 [2] 15/21 34/1

P

package [1] 143/15
packs [1] 166/12
page [133] 7/2 7/3 7/11 8/12 9/25 10/1 11/15 11/19 11/24 11/25 12/19 12/19 13/6 13/16 23/6 25/2 26/6 26/7 26/16 27/18 27/21 28/18 28/18 29/12 30/4 30/5 31/5 31/9 32/3 32/16 32/21 46/11 46/15 47/1 48/6 48/11 49/22 50/15 50/24 50/25 50/25 51/1 51/13 51/24 52/10 52/10 53/9 53/10 53/24 54/2 59/2 62/11 62/13 65/17 65/22 65/23 66/22 72/4 74/9 74/20 75/17 82/5 84/5 85/1 85/12 86/22 86/24 87/5 87/13 87/14 89/20 89/20 96/22 97/16 97/24 99/1 99/10 105/14 120/1 121/9 122/5 123/1 123/11 125/22 128/11 130/23 131/16 135/21 135/23 136/6 137/3 139/19 141/25 145/21 146/3 147/2 147/4 149/15 149/16 149/23 149/24 150/4 153/17 153/18 153/23 154/9 154/23 155/4 155/6 156/10 157/9 157/24 158/15 158/15 160/1 161/5 161/6 161/18 162/2 162/4 162/8 162/9 163/3 163/4 163/12 163/13 163/24 164/16 164/19 165/11 167/11 168/25 169/4
page 101 [1] 163/3
page 105 [1] 163/13
page 11 [1] 62/11
page 12 [2] 31/5 52/10
page 130 [1] 163/24
page 134 [1] 164/16
page 140 [1] 168/25
page 18 [1] 53/9
page 21 [1] 53/10
page 3 [3] 48/11 65/22 122/5
page 38 [1] 153/23
page 43 [1] 31/9
page 5 [2] 9/25 26/16
page 55 [1] 154/9
page 6 [1] 153/17
page 60 [1] 155/4
page 62 [1] 155/6
page 63 [1] 149/16
page 64 [1] 149/23
page 75 [1] 156/10
page 8 [1] 28/18
page 84 [1] 157/24
page 9 [2] 7/2 51/13
page 91 [1] 161/5
page 94 [1] 161/18
page 98 [1] 162/8
page, [1] 169/15
page, about [1] 169/15
pages [2] 12/18 155/6
paid [3] 11/3 22/21 62/19
pain [1] 165/10
painful [1] 39/14
panel [2] 104/25 150/25
paper [23] 14/17 14/24 15/6 15/13 46/8 46/9 47/10 48/22 48/24 49/5 49/23 53/5 54/9 74/2 74/4 84/8 122/10 161/6 161/8 161/13 163/7 163/7 163/17
papers [5] 49/19 66/23 67/10 161/17 163/6
paragraph [42] 11/23 13/5 16/21 17/1 22/24 23/12 24/10 25/3 31/15 37/18 37/18 39/1 46/4 48/13 50/16 51/5 52/2 55/7 58/21 62/12 64/7 66/23 70/17 72/6 72/10 74/5 74/6 82/7 82/21 83/2 83/10 88/5 89/11 95/3 95/9 96/23 112/6 122/23 123/1 142/1 155/6 165/15
paragraph 2 [1] 39/1
paragraphs [1] 11/24
parameters [1] 33/19
paraphrasing [1] 97/2
parcel [1] 85/24
parenteral [1] 145/16
parents [3] 97/18 165/17 165/21
part [24] 4/13 5/15 5/23 9/17 22/20 37/17 40/25 48/4 50/13 59/10 59/16 62/4 85/24 96/15 109/16 138/5 141/15 142/15 149/11 154/7 156/11 159/1 169/3 172/4
partially [1] 139/1
Participant [1] 148/24
Participants [4] 2/1 170/6 171/25 173/3
participated [2] 60/24 171/22
participating [1] 130/4
particular [35] 2/23 5/6 6/19 11/18 15/17 29/2 33/18 35/6 36/16 37/7 41/8 44/20 45/21 54/5 61/4 61/8 62/5 72/9 75/8 85/17 131/25 143/22 145/6 150/6 150/9 154/4 154/7 155/22 156/20 157/17 157/22 161/3 165/16 170/14 170/21
particularly [9] 2/18 22/23 44/9 69/6 125/20 139/11 146/13 154/4 172/4
parties [3] 141/21 149/11 153/19
partly [1] 41/23
partners [11] 118/22 118/24 120/2 120/5 120/7 120/13 120/16 120/18 131/22 132/5 150/11
parts [4] 6/9 17/4 56/22 153/13
party [18] 3/12 3/14 4/13 5/23 49/8 49/17 60/6 65/14 65/21 67/7 67/22 89/23 93/16 94/21 98/11 98/15 98/16 106/9
Party's [1] 95/1
passages [2] 9/24 169/23
passed [1] 166/19
passwords [1] 147/10
past [6] 16/11 78/8 90/19 97/9 126/1 126/16
patient [63] 8/17 9/6 10/21 14/4 14/9 14/13 14/16 17/21 19/15 21/1 24/17 29/21 36/16 37/8 37/21 52/20 53/16 72/9 78/6 79/10 79/15 80/18 84/11 84/13 84/14 87/8 87/21 89/15 96/12 96/14 96/16 98/5 108/24 114/24 117/22 119/19 126/20 127/12 128/4 128/10 128/12 133/22 134/7 136/15 137/14 141/9 142/20 143/23 145/4 145/19 146/17 147/12 147/13 147/17 148/21 148/23 149/3 153/1 159/10 160/24 165/8 165/13 168/5
patient's [8] 8/23 36/18 79/8 142/4 144/2 144/5 144/16 144/19
patient/donor [1] 133/22
patients [231]
patients' [2] 29/10 144/6
Patricia [1] 146/8
Patrick [1] 58/19
pattern [1] 25/17
Pause [1] 148/8
pausing [7] 34/21 68/25 69/15 119/11 120/7 144/21 145/24
pay [4] 19/16 57/13 57/13 107/23
PCP [1] 66/8
PCR [1] 136/3
pending [1] 115/19
penultimate [2] 62/12 70/17
people [1] 32/19
per [39] 12/11 12/13 13/3 14/3 14/4 14/9 14/9 14/12 14/15 15/2 15/2 15/4 15/4 15/7 15/8 15/14 15/16 15/18 18/6 29/21 33/7 35/20 44/16 48/16 48/19 48/21 91/11 96/2 100/25 104/14 114/4 116/8 120/12 129/4 129/5 129/6 131/4 167/6 167/6
perceived [3] 155/12 162/21 168/18
perception [4] 38/10 159/8 160/22 161/1
performed [1] 44/9
perhaps [21] 9/12 19/15 26/25 28/12 41/10 54/1 54/23 61/18 65/15 74/17 79/22 82/12 84/2 85/3 86/10 87/22 94/23 132/17 141/1 168/15 169/23
period [16] 2/23 11/17 14/10 14/25 15/10 34/9 68/6 79/25 91/6 113/25 114/9 115/22 117/2 118/14 121/12 161/4
peripherally [1] 59/6
permission [1] 30/12
persist [1] 22/10
persistently [1] 155/21
person [5] 125/9 125/13 126/21 131/25 172/20
personal [2] 22/5 146/9
personally [1] 115/11
personnel [2] 4/25 40/18
persons [2] 140/7 150/15
perspective [8] 11/8 23/11 23/24 33/3 55/5 71/23 89/2 155/2
perspectives [2] 65/7 88/2
perturbed [1] 137/8

P

PFC [1] 105/3
PFL [9] 2/9 5/13 6/11 9/18 15/12 16/17 33/13 89/5 127/23
Philip [1] 45/7
PHLS [4] 74/11 128/3 128/7 158/10
physician [2] 64/16 64/24
physicians [1] 8/20
physiotherapists [1] 8/21
pick [8] 22/13 27/21 30/5 42/25 56/3 64/6 83/9 106/22
picking [5] 23/12 37/17 50/15 52/11 93/8
picture [4] 2/4 38/3 38/16 141/11
pioneered [4] 8/10 29/2 29/3 40/17
pity [1] 40/21
place [5] 26/25 42/17 71/20 108/8 121/16
placebo [1] 27/19
placed [4] 107/15 147/1 152/1 159/13
plainly [1] 35/7
plan [3] 41/13 81/18 97/11
planned [1] 20/5
planning [2] 27/3 80/13
plans [3] 40/2 84/24 89/23
plasma [44] 2/8 5/3 7/7 7/13 8/1 10/11 10/13 10/14 10/16 10/24 11/3 11/4 11/5 12/2 12/15 12/23 12/24 25/6 25/8 29/18 31/19 31/24 31/25 32/10 32/25 39/7 40/19 52/14 52/16 52/18 52/21 53/15 54/4 62/18 70/5 70/19 71/4 101/12 105/17 112/1 154/19 159/18 167/12 167/15
plasmapheresis [1] 11/3
plastic [1] 56/18
platelet [1] 66/18
played [2] 1/18 3/18
please [55] 6/21 6/22 7/2 8/8 8/12 9/21 9/25 11/19 11/24 15/21 16/7 21/6 22/2 25/24 26/16 28/18 31/1 31/9 34/10 34/11 36/14 43/2 45/1 48/11 51/1 62/8 64/2 65/15 84/5 86/11 86/24 90/12 93/9 99/20 100/6 111/5 111/7 112/6 113/14 115/25 120/22 121/22 127/22 130/23 133/3 137/18 148/8 149/16 153/17 154/9 155/6 157/9 158/19 162/2 164/16
pleased [2] 114/6 128/8
pm [5] 99/21 99/23 148/3 148/5 173/7
point [20] 11/18 15/18 22/4 34/24 42/9 51/10 53/5 53/8 53/11 53/13 54/2 57/24 58/13 74/2 99/17 113/7 114/17 117/17 155/3 167/11
point 2 [1] 53/11
point 5 [1] 54/2
pointed [2] 34/22 35/1
points [2] 53/18 92/10
policies [1] 36/12
policy [21] 28/21 28/22 29/10 38/4 38/9 45/25 47/2 55/5 70/6 70/19 70/25 71/5 71/11 72/16 73/11 73/21 85/18 122/9 122/11 122/21 137/17
political [1] 74/21
pool [18] 7/15 11/9 11/16 32/25 38/11 46/19 47/1 47/14 47/17 52/16 54/5 62/14 63/5 88/25 101/11 101/13 154/11 154/19
pooled [2] 154/15 166/13
pools [7] 10/23 10/24 47/16 52/13 52/15 54/3 62/18
poor [2] 29/9 62/19
poorly [1] 162/4
population [5] 81/9 81/22 112/22 134/16 166/20
pose [2] 140/9 140/14
posed [1] 122/13
poses [2] 56/24 140/7
position [17] 1/14 3/6 14/18 21/12 24/24 29/8 32/22 61/12 83/24 113/12 114/19 115/21 122/2 133/19 136/23 154/5 172/3
positive [30] 47/3 114/25 119/3 119/4 120/6 120/13 120/16 120/17 123/13 123/17 124/1 127/11 127/13 129/7 129/18 131/2 131/8 132/1 132/2 132/4 133/9 133/16 133/17 135/21 135/24 136/16 136/19 140/5 150/14 152/7
positives [2] 136/4 136/5
possibility [5] 63/10 63/22 75/25 92/8 140/16
possible [35] 1/16 2/2 24/8 27/25 37/11 38/6 41/9 45/3 45/7 45/9 46/16 63/17 64/20 66/10 69/3 70/2 70/8 71/2 74/15 78/5 78/25 79/2 79/6 89/8 94/1 102/9 107/12 109/7 126/11 127/4 131/10 144/7 145/16 159/6 166/8
possibly [7] 23/5 38/14 38/15 67/4 88/10 110/14 165/10
post [1] 156/17
postal [1] 169/9
potency [1] 10/18
Potency' [1] 10/23
potential [9] 46/24 59/10 61/10 78/20 87/20 99/9 112/22 125/7 170/19
potentially [6] 17/22 72/14 78/12 87/7 165/3 170/10
practicable [1] 162/25
practical [2] 81/5 166/23
Practically [1] 24/16
practice [10] 17/23 39/19 47/4 107/7 158/25 160/8 160/12 160/14 168/13 169/19
practices [1] 24/3
practitioner [2] 6/25 8/19
pre [1] 20/18
precaution [1] 140/9
precise [5] 48/24 69/23 117/18 128/20 151/9
precisely [3] 97/21 109/15 109/18
predictably [1] 52/17
predicting [1] 40/12
predicts [1] 41/16
predisposing [1] 66/5
prefer [3] 30/20 43/25 137/22
preferably [1] 97/7
preference [2] 32/25 36/10
preferences [1] 145/16
preferential [1] 55/12
preferentially [1] 69/22
preliminary [3] 82/18 92/14 101/5
preparation [14] 10/23 13/11 44/21 47/7 50/10 51/7 51/11 52/21 53/24 90/17 92/9 96/1 104/10 105/10
preparations [19] 7/24 13/20 13/23 17/11 30/8 35/17 39/2 39/6 39/8 44/14 44/22 53/16 53/22 54/17 88/10 90/21 104/22 114/12 115/6
prepare [1] 26/21
prepared [22] 6/3 6/5 6/9 7/17 7/25 33/20 46/19 92/21 103/5 104/12 104/24 113/22 114/9 115/11 115/20 132/8 134/23 154/16 155/9 159/16 167/22 168/1
Preparing [1] 49/18
preponderance [1] 51/6
presence [1] 152/9
present [34] 10/24 13/10 16/14 17/20 21/12 24/12 24/14 26/2 26/4 31/6 31/8 34/17 39/9 39/15 39/21 44/2 44/16 45/22 46/12 46/21 47/2 50/1 50/12 50/21 56/13 57/6 63/15 68/5 84/4 102/8 104/9 114/22 129/18 151/8
presentation [17] 1/3 5/7 6/7 34/22 58/12 61/14 69/3 73/6 74/17 76/8 79/4 149/7 151/3 153/21 170/5 172/7 174/2
presented [7] 46/9 46/9 47/11 64/21 68/16 141/12 152/7
presenting [1] 84/7
presently [1] 7/6
press [1] 109/1
pressing [2] 30/12 71/7
pressure [3] 40/14 108/25 109/7
pressures [1] 16/5
Preston [1] 156/4
presumably [19] 15/10 18/20 18/22 25/7 35/10 41/2 63/3 79/2 79/9 80/7 85/24 93/12 112/16 115/16 122/17 149/19 159/23 160/3 162/17
prevalence [3] 111/20 112/21 162/10
preventable [1] 109/5
prevented [1] 9/7
previous [13] 48/6 76/16 93/18 97/9 102/5 106/2 118/11 135/15 135/16 135/17 136/10 143/19 159/25
previously [12] 12/15 87/24 88/25 90/23 91/3 96/9 96/16 102/13 103/7 104/17 115/3 136/18
price [2] 35/19 35/21
primarily [1] 162/19
printout [4] 116/24 117/3 118/12 118/15
prior [5] 96/19 97/6 100/3 100/8 137/10
priority [1] 13/25
privately [1] 76/23
probability [2] 54/5 75/25
probably [16] 1/23 10/21 32/24 49/13 51/1 57/13 58/2 73/16 77/18 114/15 126/5 126/6 155/12 158/3 158/9 162/14
problem [18] 30/8 36/24 50/17 54/25 59/4 64/12 64/22 91/1 116/9 124/16 126/16 131/10 155/13 156/12 156/19 158/23 164/8 166/23
problem's [1] 127/1
problematic [1] 52/8
problems [8] 31/17 74/21 107/6 130/15 139/2 140/13 158/6 169/10
procedure [5] 52/3 95/19 97/15 117/7 117/19
procedures [3] 91/12 126/17 172/5
proceed [1] 136/3
process [7] 51/24 81/4 82/6 88/13 118/5 125/12 141/22
processed [2] 40/8 88/11
produce [5] 1/24 51/16 70/21 71/1 91/16
produced [8] 44/13 86/4 89/5 112/2 114/7 133/13 147/21 153/14
product [41] 15/8 15/10 30/10 30/13 32/10 33/22 34/7 39/21 40/7 41/1 44/1 45/10 46/5 55/6 75/4 75/5 75/15 77/6 86/8 89/9 90/9 91/22 93/16 93/24 94/5 94/7 97/11 103/12 104/11 104/15 105/24 106/3 106/11 110/5 110/7 113/20 115/13 115/14 115/16 125/14 140/5
production [8] 50/13 52/1 70/23 71/7 85/24 159/17 167/12 167/17
productive [1] 73/19
products [66] 5/21 6/13 6/18 33/4 36/8 36/13 39/4 40/5 40/19 40/24 41/12 44/11 49/3 59/15 63/10 63/18 66/11 67/25 73/20 73/24 87/7 87/21 89/13 89/24 90/2 93/17 94/1 94/9 94/13 95/6 96/18 97/6 101/22 102/3 103/1 103/24 104/9 104/19 104/21 105/16 105/21 106/7 106/18 106/21 107/19 109/17 111/3 111/14 112/24 121/12 122/4 126/2 128/4 141/4 142/16 151/23 152/5 156/20 157/17 157/22 163/23 164/25 165/14 169/18 170/16 170/23
professionals [1] 42/4
Professor [51] 1/8 4/15 32/4 32/13 32/14 33/15 33/16 42/21 42/25 43/3 55/22 58/13 58/14 58/17 59/3 63/16 72/19 72/24 73/6 73/7 73/13 73/15 74/24 75/19 76/3 76/4 76/5 76/8 76/14 79/9 79/18 79/23 80/3 82/14

P

Professor... [17] 83/13 83/22 85/13 86/15 89/14 93/10 103/22 128/23 130/11 130/14 130/24 151/4 151/5 151/6 162/18 172/17 172/18
Professor Blackburn [2] 42/21 43/3
Professor Blackburn's [1] 42/25
Professor Bloom [28] 4/15 58/13 58/14 58/17 59/3 63/16 72/19 72/24 73/6 73/13 73/15 76/3 76/4 76/5 76/8 76/14 79/9 79/18 79/23 85/13 86/15 89/14 93/10 103/22 151/4 151/5 151/6 162/18
Professor Bloom's [1] 73/7
Professor Christine [1] 172/17
Professor Giangrande [1] 1/8
Professor Ingram [2] 33/15 55/22
Professor Lechner [1] 74/24
Professor Lee [7] 32/4 32/13 32/14 80/3 82/14 83/13 83/22
Profilate [2] 34/19 34/23
prognosis [1] 159/12
programme [7] 14/11 29/6 30/24 68/18 100/16 128/18 159/7
progress [2] 77/23 90/16
progression [1] 121/18
project [1] 5/12
prolonged [1] 165/9
promiscuous [1] 157/14
promised [2] 102/20 131/19
proof [2] 93/3 163/11
prophylactic [8] 25/1 26/19 26/22 26/24 27/8 28/10 28/16 53/9
prophylaxis [3] 24/14 24/20 27/12
proportion [3] 12/14 114/3 140/4
proposal [9] 28/14 45/2 45/12 71/8 85/7 93/23 95/1 96/5 98/13
proposals [4] 85/10 86/16 87/14 87/19
propose [1] 93/12
proposed [3] 102/10 133/4 134/5
proposes [1] 101/15
pros [1] 57/11
prospect [2] 114/12 127/18
prospective [6] 62/2 87/18 98/20 100/10 102/4 102/10
prospectively [1] 97/11
Protection [1] 147/15
protective [1] 132/1
protein [1] 7/25
protocol [12] 26/21 27/2 27/5 93/15 94/11 94/24 96/5 99/13 99/24 100/3 101/24 103/9
protocols [1] 172/5
prove [1] 92/16
provide [9] 55/13 116/10 118/21 127/7 139/16 139/24 163/19 167/4 171/21
provided [19] 8/25 16/2 58/23 78/17 92/19 103/22 106/8 129/9 138/3 139/10 142/19 149/1 153/10 161/4 167/10 170/6 171/4 171/7 171/18
provides [2] 22/20 154/8
providing [1] 91/16
provision [5] 50/12 56/13 56/17 107/23 169/1
Provisional [1] 116/21
proximity [1] 12/22
PRSE0000476 [1] 115/25
PRSE0000609 [1] 90/12
PRSE0001917 [1] 111/5
PRSE0002350 [1] 49/14
PRSE0002515 [1] 55/21
PRSE0003912 [1] 116/17
PRSE0004645 [2] 9/21 62/9
PRSE0004706 [1] 45/18
psychiatric [1] 123/21
psychological [2] 123/13 123/16
public [1] 109/1
publication [5] 6/22 52/25 60/18 120/25 123/7
publications [1] 158/1
publicised [1] 64/19
publicity [2] 68/19 125/20
publicly [2] 76/22 127/6
published [2] 55/24 55/25
punch [4] 148/21 148/22 148/25 149/1
punch cards [1] 148/21
purchase [12] 19/2 20/14 21/5 22/2 30/7 30/13 40/23 41/18 47/24 48/1 58/25 109/14
purchased [1] 112/16
purchaser [1] 35/11
purely [1] 109/3
purification [1] 11/7
purpose [2] 49/23 92/25
purposes [10] 31/6 45/21 46/12 72/22 77/1 83/14 91/25 148/17 149/2 153/14
pursue [2] 107/14 131/9
pushed [1] 32/6
pushing [1] 90/20
put [7] 15/20 36/13 126/13 127/3 146/20 159/10 160/24
putative [1] 105/18
putting [1] 173/5

Q

quality [8] 30/9 43/21 56/11 88/19 108/17 108/20 159/5 165/12
quantified [1] 45/9
quantities [3] 41/11 58/25 142/16
quantity [1] 39/20
Queen [2] 6/17 57/25
Queen Elizabeth [1] 6/17
question [14] 30/2 32/4 39/1 56/4 56/24 108/1 115/18 122/24 137/5 145/14 148/6 160/25 165/7 165/19
questionnaire [1] 112/10
questions [5] 131/24 144/18 163/21 170/2 170/12
quick [1] 39/13
quickly [2] 68/22 131/10
quite [10] 4/4 18/2 49/9 50/19 64/13 64/22 84/23 144/9 152/24 165/6
quoted [2] 48/14 48/19
quotes [1] 48/19

R

Radcliffe [5] 5/16 5/17 19/9 131/18 135/7
Rainsford [1] 27/3
raise [1] 92/10
raised [9] 64/8 130/14 131/24 153/9 155/23 158/7 158/9 158/13 158/14
raises [2] 23/8 149/2
random [1] 91/8
range [4] 3/8 123/16 128/20 148/22
ranging [1] 108/8
rapidly [4] 21/13 33/7 45/3 166/24
rare [1] 8/24
rate [6] 68/6 96/2 104/14 121/17 130/21 131/3
rather [5] 12/25 82/15 115/11 137/23 168/2
ratios [4] 67/12 67/13 80/9 80/16
raw [3] 146/5 159/16 167/12
reach [2] 106/15 168/25
reached [2] 33/17 67/21
reaction [1] 54/22
reactions [2] 48/8 166/14
reactivity [1] 49/3
read [7] 8/14 9/11 35/9 88/6 111/6 144/22 169/25
readily [1] 134/16
reading [1] 8/5
reality [1] 82/9
really [6] 3/6 27/6 32/6 51/24 59/18 61/17
reappraised [1] 104/8
reason [10] 9/2 38/9 38/10 40/3 48/18 57/2 59/17 69/7 147/22 147/22
reasonable [5] 17/23 56/6 126/8 168/13 168/18
reasoning [1] 168/22
reasons [8] 89/18 89/18 104/18 115/10 124/21 135/25 160/13 160/19
reassess [1] 41/11
recall [8] 33/16 42/19 58/12 63/14 86/12 100/1 168/4 172/6
recalled [1] 47/18
receipt [2] 60/5 151/21
receive [5] 25/9 37/5 84/10 107/10 170/10
received [34] 16/20 36/25 37/3 37/22 60/21 64/16 68/15 69/13 78/9 79/10 79/15 81/13 81/14 84/14 84/16 93/5 95/20 96/18 97/6 97/8 101/10 104/16 112/10 116/7 117/11 119/22 120/13 121/12 129/23 132/25 138/18 141/17 168/4 169/11
receiving [15] 5/21 14/14 25/21 27/8 33/8 36/24 37/23 81/7 95/22 110/6 114/23 129/21 129/21 152/18 168/2
recent [8] 29/15 36/22 50/10 68/19 95/4 117/5 118/17 128/12
recently [6] 17/4 40/2 44/12 68/16 104/8 136/16
recipients [2] 157/16 157/21
recognised [1] 161/15
recognises [1] 93/19
recognition [2] 46/24 157/10
recollection [1] 110/8
recommend [3] 36/5 106/17 168/10
recommendation [3] 53/25 67/24 169/13
recommendations [8] 47/21 47/22 112/7 133/15 158/22 160/11 163/1 169/5
recommended [3] 85/18 162/24 162/25
recommended ... for [1] 162/24
recommending [1] 162/19
reconcile [1] 132/11
reconstitute [1] 166/12
reconstitution [1] 51/19
record [4] 61/8 63/2 79/14 84/7
recorded [5] 63/16 87/6 99/13 123/14 139/20
recording [1] 116/14
records [13] 36/25 60/21 79/13 136/25 137/2 137/6 138/4 145/15 152/23 153/3 153/5 153/8 153/8
recovery [2] 39/13 53/15
recruited [1] 91/7
recurrent [1] 19/17
red [2] 13/1 41/2
redacted [2] 36/16 127/4
reduce [5] 19/20 23/16 88/12 89/9 92/22
reduced [14] 86/17 86/21 87/7 88/22 90/5 90/17 91/1 93/14 95/1 95/4 99/25 100/3 159/4 159/21
reduced' [2] 96/8 104/4
reducing [1] 57/9
reduction [1] 25/14
refer [2] 61/21 102/14
reference [56] 20/11 28/20 29/7 38/1 48/8 48/25 52/25 60/3 60/11 62/25 63/12 63/21 66/22 67/13 71/4 71/19 72/5 73/22 76/21 77/9 79/2 84/1 85/13 85/15 86/15 88/14 93/7 95/14 98/8 100/1 101/3 105/5 107/4 107/17 111/12 112/4 122/8 123/11 125/5 128/5 137/1 137/11 139/3 145/19 147/16 150/5 150/5 158/7 160/3 160/4 161/6 161/19 162/9 162/18 163/3 163/13
referred [12] 2/22 27/22 30/17 76/16 79/13 85/2 94/24 99/6 133/18 134/21 137/15 149/6
referring [3] 17/18 127/5 163/6
refers [15] 7/15 22/24

R

refers... [13] 31/15 32/19 43/9 44/11 56/18 95/3 107/8 155/24 156/3 156/6 158/16 163/1 164/3
reflected [2] 26/15 58/8
reflecting [1] 63/5
reflection [6] 28/12 42/6 47/12 54/20 82/19 110/18
reflects [1] 12/21
refused [1] 23/22
regard [9] 35/19 64/9 77/20 79/19 95/7 112/24 125/10 125/11 154/13
regarding [6] 74/14 74/22 84/6 84/8 92/8 140/3
regardless [1] 27/13
regards [1] 3/4
region [7] 16/20 17/3 19/3 21/14 23/25 43/22 138/25
regional [15] 2/10 10/14 12/9 12/23 16/15 22/20 22/21 43/20 68/12 68/13 121/20 121/23 122/21 133/14 143/9
regions [1] 18/9
register [1] 117/21
registered [1] 142/5
Registrar [1] 124/17
registrars [1] 124/18
registration [2] 119/10 119/15
regular [4] 14/14 27/13 60/2 60/5
regulation [1] 80/23
regulatory [2] 91/17 92/11
reiterate [1] 108/7
rejecting [1] 47/2
relate [1] 1/16
related [7] 3/22 48/16 121/6 123/16 139/2 144/15 152/4
relating [11] 1/10 1/21 4/12 61/1 63/25 83/25 121/20 141/1 151/3 151/20 153/10
relation [47] 1/15 1/19 2/23 4/14 5/25 9/15 11/10 11/15 15/21 36/15 45/14 46/17 55/6 58/9 58/12 60/21 61/12 61/20 64/5 67/24 68/9 68/9 74/8 82/25 83/24 86/6 86/8 86/17 91/19 91/23 99/12 103/11 103/24 105/12 113/7 113/20 120/2 129/17 132/24 136/23 138/2 141/9 153/2 168/22 170/8 172/3 172/5
relationship [2] 63/18 150/22
relative [9] 11/9 14/18 38/11 63/4 70/11 81/1 83/19 154/11 154/13
relatively [3] 9/19 25/24 126/24
relatives [3] 125/19 137/15 151/14
released [1] 115/9
releasing [1] 113/21
relevance [1] 46/25
relevant [8] 45/21 51/24 70/14 72/25 88/6 119/15 138/11 157/8
reluctance [1] 23/1
reluctant [1] 114/13
rely [1] 16/14
remain [1] 99/3
remainder [1] 135/22
remaining [2] 128/9 129/20
remedied [1] 40/11
remember [1] 136/15
remembered [1] 91/9
remote [1] 63/22
renders [1] 56/16
repeated [2] 113/2 118/5
repetition [1] 162/3
replace [1] 13/23
replacement [1] 91/12
replies [1] 112/10
reply [2] 24/2 103/3
report [38] 1/24 4/6 6/2 6/9 51/2 61/12 61/15 62/9 65/11 66/17 67/9 85/20 86/1 116/3 116/17 116/21 118/7 120/24 121/7 127/2 127/7 127/19 138/10 142/10 147/21 153/13 153/16 153/25 154/10 155/9 157/10 161/2 161/20 162/5 163/25 164/6 169/24 169/25
reported [8] 68/7 106/11 110/9 111/18 120/2 124/22 124/23 127/10
reporting [9] 11/12 66/3 67/1 67/3 67/15 67/23 85/7 85/8 123/15
reports [7] 60/6 116/7 117/11 119/22 120/13 147/4 158/11
represent [1] 173/2
representations [2] 19/19 21/24
representative [1] 72/3
representatives [1] 170/7
represented [3] 65/20 77/8 112/14
representing [1] 45/23
reprinted [1] 6/24
request [9] 5/20 6/10 18/11 21/2 89/25 102/24 116/5 144/5 145/23
requesting [1] 143/15
requests [1] 6/18
require [6] 17/10 91/12 93/21 100/21 106/3 147/9
required [10] 29/21 29/24 39/20 44/2 51/18 82/3 82/4 126/5 137/16 144/12
requirements [6] 15/11 20/17 45/5 45/10 58/4 147/17
requires [1] 8/18
requiring [3] 18/10 88/24 130/1
research [34] 1/19 1/21 2/3 2/4 2/7 3/4 3/12 3/14 4/3 4/19 5/2 5/4 5/24 49/7 49/8 49/17 61/2 100/4 100/15 121/1 138/9 141/1 141/3 141/4 141/7 141/11 148/6 149/5 149/20 150/7 150/17 152/13 159/19 171/22
resentment [1] 23/21
reserve [1] 38/6
reserved [2] 8/2 37/12
residual [4] 39/14 95/3 95/10 96/7
resource [1] 56/22
respect [8] 1/23 41/22 46/1 76/8 77/24 90/1 127/8 144/25
respective [2] 3/5 106/1
respects [2] 2/19 3/6
responded [1] 32/1
responds [1] 32/7
response [16] 22/3 36/17 36/19 55/22 59/8 65/7 86/14 86/14 92/5 107/21 107/22 130/22 156/11 163/25 164/14 170/25
responsible [2] 56/21 96/13
rested [1] 116/16
restrict [2] 23/1 24/8
restriction [3] 23/9 23/18 72/12
result [17] 100/11 117/5 118/17 119/1 125/9 125/14 125/15 128/3 131/8 134/21 134/25 135/21 135/24 140/5 140/11 144/20 159/19
resulted [3] 72/18 89/9 167/14
results [37] 70/5 70/18 70/20 81/9 82/18 83/1 83/3 83/7 95/25 99/11 104/13 116/12 116/13 116/15 117/10 117/18 117/22 119/21 120/1 125/20 128/23 128/25 129/11 132/8 132/17 132/18 132/23 133/9 135/14 135/20 136/2 136/12 136/13 136/14 152/25 161/12 171/17
retirement [1] 4/24
retrieved [1] 147/7
retrospective [1] 41/24
retrospectively [1] 65/11
retrovirus [2] 161/10 163/15
return [5] 62/6 74/18 117/6 137/12 137/14
return's [1] 142/13
returns [8] 5/6 12/4 19/11 141/17 141/20 142/14 142/15 147/14
revealed [2] 131/3 156/1
reversion [2] 25/20 71/11
review [1] 150/7
reviewed [2] 16/4 65/25
revolutionised [1] 50/10
rhetorical [1] 56/24
RICHARDS [4] 1/3 172/9 173/2 174/2
ridiculous [1] 57/16
right [10] 24/16 32/5 35/2 48/23 56/3 58/18 99/16 137/1 160/8 161/16
right-hand [1] 56/3
rightly [1] 34/21
rise [2] 110/13 161/13
rising [2] 15/8 111/21
risk [32] 17/16 37/16 46/20 46/25 63/4 63/7 68/23 69/10 77/5 88/12 89/9 90/25 92/23 95/8 100/22 101/21 102/9 105/18 108/14 113/8 130/17 131/14 140/8 140/9 140/14 157/15 157/20 159/11 159/22 159/22 160/24 170/25
risks [18] 3/5 59/25 62/3 62/15 63/4 70/11 81/1 83/19 151/22 154/11 154/13 165/9 168/19 170/15 170/22 171/8 171/11 171/12
risky [1] 71/9
Rizza [176]
Rizza's [34] 24/1 33/14 34/24 36/9 36/18 38/4 60/1 61/11 63/3 63/25 65/18 68/9 83/24 91/21 103/3 113/12 115/21 127/2 130/22 138/10 149/9 153/13 155/2 156/15 157/10 158/12 160/7 161/2 161/8 163/17 163/25 168/22 169/24 170/15
RLIT0000022 [1] 31/1
road [1] 124/25
Robin [1] 163/5
Rogers [1] 45/7
role [9] 1/19 2/18 3/18 5/5 9/13 31/20 82/22 149/9 151/9
roles [1] 60/1
room [2] 64/25 146/21
rose [1] 15/4
Rosemary [4] 4/22 5/4 9/22 45/22
round [1] 70/24
route [1] 70/14
routine [1] 167/22
routinely [1] 114/24
Royal [8] 6/16 28/24 29/4 32/14 32/17 80/9 83/17 172/21
Royal Free [8] 6/16 28/24 29/4 32/14 32/17 80/9 83/17 172/21
RTC [1] 134/2
rumour [1] 75/2
rumoured [1] 70/24
run [3] 35/19 57/12 108/14
runs [1] 141/15

S

safe [6] 87/3 89/13 139/25 166/21 167/17 172/24
safeguards [2] 91/17 92/12
safely [2] 140/19 166/25
safer [3] 38/11 83/12 114/15
safety [10] 51/15 74/13 75/10 95/6 111/13 112/23 138/24 169/18 169/21 171/10
said [34] 24/25 26/9 26/22 28/7 30/5 38/5 47/3 54/21 58/21 59/2 63/18 66/15 67/11 69/10 70/25 78/24 79/8 83/2 95/5 97/16 103/4 105/15 116/8 116/10 119/6 119/17 122/10 122/23 132/20 133/22 142/3 147/8 161/7 163/21
sale [2] 41/3 41/4
same [15] 55/17 57/19 57/20 57/24 70/4 79/15 80/2 84/10 96/21 117/7 131/15 140/18 161/15 162/1 162/3
sample [6] 10/17 109/25 122/14 123/19 128/9 134/20
samples [15] 78/4 78/16 80/7 98/13 98/17 122/16 122/24 122/25 123/3 127/12 127/16 128/2 128/7 128/9 136/15
sampling [1] 128/18
San [1] 66/21
San Francisco [1] 66/21
sarcoma [1] 66/8
sat [1] 173/3
satisfactory [3] 13/19 44/15 51/21
satisfied [1] 91/18
satisfy [1] 92/18
saw [1] 33/4
say [32] 1/18 11/12 22/1 28/16 32/24 35/5 43/15 54/11 68/17 70/1 73/15 76/18 83/20 89/6 89/20

S

say... [17] 105/20 108/12 112/19 113/3 125/17 127/1 127/17 130/19 131/6 131/13 152/17 154/20 155/7 155/7 155/12 165/24 167/25
saying [9] 22/15 73/15 74/10 76/9 76/22 126/15 132/16 157/12 168/5
says [73] 7/16 7/22 8/15 10/2 13/6 13/17 16/9 16/21 20/12 20/20 22/4 22/25 23/6 24/11 25/3 34/15 35/15 38/25 39/5 39/18 39/24 40/16 50/7 50/16 50/18 51/9 59/12 59/12 61/14 69/5 77/16 77/25 80/13 81/6 81/16 82/18 85/19 92/13 93/25 107/13 112/6 113/20 114/5 116/4 124/13 125/6 125/22 126/12 128/6 128/15 129/15 130/24 135/24 140/1 145/1 154/12 154/23 158/20 159/15 160/2 162/6 162/15 165/5 165/12 165/15 166/3 166/4 166/18 166/22 167/9 168/16 169/4 169/16
scale [5] 51/18 51/21 106/18 159/4 167/16
scarce [1] 39/9
Science [1] 161/7
scientist [2] 5/2 5/13
scope [1] 45/10
Scottish [2] 90/10 102/17
screen [7] 8/5 15/20 36/13 72/21 127/3 134/1 154/8
screening [7] 54/8 68/18 68/22 70/9 71/9 113/10 122/9
search [1] 163/11
second [27] 16/21 25/2 36/10 48/13 50/16 52/2 56/16 59/20 64/7 72/4 72/6 75/12 75/17 78/24 83/10 86/5 86/24 105/7 121/9 123/1 124/5 127/2 130/23 131/16 141/24 150/20 151/24
secondly [2] 2/22 94/19
secretary [7] 3/11 3/19 3/19 58/14 72/25 124/14 146/9
secretary-general [1] 3/19
section [7] 51/2 153/24 154/10 155/4 156/11 157/10 163/24
secured [1] 110/3
Security [3] 9/3 30/17 129/14
see [143] 5/21 7/2 7/11 7/15 8/12 10/2 11/14 11/21 13/12 14/19 18/11 19/4 19/11 19/22 21/17 22/14 23/10 24/24 25/16 26/2 28/21 29/7 30/23 31/5 32/3 32/4 32/21 33/10 34/2 35/14 37/7 37/17 38/18 42/22 45/1 45/19 46/4 46/8 47/20 48/2 48/23 49/15 49/22 49/23 53/4 55/4 57/21 57/23 58/20 59/14 60/14 60/19 62/8 62/12 62/13 63/23 65/18 66/3 66/22 68/25 69/20 70/10 70/22 71/17 72/1 73/8 74/10 75/1 75/6 78/9 83/15 84/3 84/7 86/17 87/5 87/13 87/15 88/5 90/8 91/1 93/9 94/25 100/14 101/9 101/24 103/2 103/10 103/15 103/25 105/14 108/3 109/12 109/24 110/17 111/9 113/19 114/19 115/14 115/21 116/13 117/19 117/23 120/1 120/23 121/9 121/23 122/5 122/23 126/18 126/25 127/23 128/22 130/10 130/13 131/12 131/14 132/9 133/4 134/7 135/5 135/14 135/20 136/21 139/14 142/1 143/13 144/8 145/15 146/3 149/18 149/20 149/23 149/25 150/5 153/18 154/9 157/12 160/1 161/2 161/18 163/13 164/2 172/25
seeing [2] 5/17 172/23
seek [3] 41/18 73/23 82/15
seeking [1] 45/25
seem [10] 18/25 20/16 40/20 48/16 52/24 53/6 54/18 78/21 132/13 151/1
seemed [6] 33/1 66/10 119/11 155/14 155/15 155/17
seemingly [3] 16/22 82/18 87/20
seems [7] 18/2 20/15 22/10 29/1 136/1 136/9 148/24
seen [19] 12/6 19/19 38/2 38/19 59/24 60/23 61/17 70/10 77/7 79/12 79/14 86/9 107/18 138/19 141/3 141/14 145/3 146/22 148/13
selected [2] 96/25 104/25
self [9] 30/11 38/17 38/18 41/15 41/25 45/16 48/3 58/11 155/16
self-limiting [1] 155/16
self-sufficiency [8] 30/11 38/17 38/18 41/15 41/25 45/16 48/3 58/11
sell [1] 56/11
selling [1] 84/21
seminar [2] 31/3 31/8
send [3] 73/3 93/10 93/12
sending [3] 80/7 82/17 167/15
sends [1] 104/2
senior [1] 64/23
sensitive [1] 146/13
sent [33] 21/9 21/10 27/2 36/15 72/19 72/23 78/2 78/15 88/3 98/23 99/13 116/24 116/25 117/13 117/20 118/12 119/8 119/12 119/24 120/3 133/5 142/10 143/1 143/8 143/11 143/14 145/22 145/25 146/6 146/18 146/23 147/12 169/8
sentence [6] 17/1 54/12 70/17 75/17 82/20 83/9
separate [1] 137/2
separately [1] 12/5
September [17] 63/13 64/3 84/1 100/7 106/10 113/23 116/2 116/14 133/7 136/8 138/14 142/24 158/6 158/13 161/20 162/3 163/14
September 1983 [2] 84/1 161/20
September 1984 [1] 106/10
September 1985 [1] 116/14
sequelae [2] 61/10 101/21
sera [4] 98/9 98/18 98/23 135/18
series [1] 97/12
serious [2] 28/9 156/8
seriously [1] 89/16
seriousness [4] 61/16 170/19 171/11 171/12
sero [1] 114/24
sero-converted [1] 114/24
seroconversion [2] 111/23 127/14
seroconversions [1] 121/15
seroconverted [1] 135/24
serological [1] 131/3
seropositive [1] 121/15
Seropositivity [1] 121/5
serum [2] 98/13 127/12
serve [1] 40/20
served [1] 150/20
service [17] 9/1 12/23 22/20 31/21 46/22 52/6 90/11 102/17 108/9 122/9 133/7 139/11 139/23 139/25 140/21 140/22 159/14
Service's [1] 4/8
services [2] 62/24 87/2
set [27] 8/13 10/8 11/22 30/17 43/12 45/15 46/2 68/18 68/22 69/6 70/8 80/9 81/5 89/19 90/3 96/15 106/5 115/5 115/21 123/20 133/20 135/2 135/3 142/15 156/15 163/12 164/9
sets [9] 10/10 12/1 82/2 82/3 114/19 134/24 164/19 165/4 166/11
setting [4] 2/1 80/12 81/18 113/19
settle [1] 154/22
seven [5] 14/7 14/21 55/18 101/10 143/20
seventeen [1] 44/6
several [10] 11/1 25/12 47/4 89/17 101/22 117/12 119/23 131/23 166/10 166/12
severe [6] 37/13 66/6 80/18 130/1 134/13 165/9
severely [4] 14/1 47/5 103/15 162/19
severity [1] 61/9
sex [1] 144/2
sexual [10] 118/22 118/24 120/2 120/5 125/10 131/1 131/14 132/5 134/16 145/16
shall [5] 40/9 42/11 108/24 114/6 148/1
shared [4] 1/25 87/16 148/16 148/23
shares [1] 103/9
sharing [2] 148/7 149/3
sharp [1] 27/9
she [55] 5/19 5/22 10/2 10/9 10/20 11/12 11/14 12/1 12/4 13/6 13/17 13/17 14/6 19/24 20/12 20/20 20/25 21/9 21/10 26/21 26/23 27/1 28/7 29/15 38/19 38/25 39/5 39/18 39/23 40/12 40/16 41/4 41/16 50/6 50/16 51/4 51/9 52/5 52/9 55/17 55/18 55/19 55/19 56/18 56/24 57/11 63/1 64/12 80/13 82/2 82/3 82/14 82/17 83/14 136/15
shed [1] 83/21
sheets [1] 146/16
SHO [1] 139/20
short [11] 8/1 16/23 22/3 37/11 39/8 42/14 102/6 102/13 112/10 148/4 166/4
shortage [10] 17/5 24/15 28/13 31/17 39/25 40/3 40/11 44/8 56/5 56/25
shortages [5] 16/6 26/17 38/5 42/17 58/11
shortfall [2] 58/22 59/23
shortly [6] 44/22 64/2 64/15 105/4 105/21 169/8
should [56] 1/18 8/16 17/25 25/14 25/19 27/23 39/17 41/24 44/22 45/9 53/20 55/9 56/4 59/4 65/2 65/8 65/22 67/7 70/2 74/17 75/9 77/12 82/11 84/12 84/21 86/25 87/25 91/9 101/1 102/14 103/13 105/7 107/10 107/11 107/14 122/14 124/20 129/7 133/17 133/21 134/7 134/9 140/9 140/16 140/17 146/19 149/12 150/10 152/16 153/15 155/7 156/7 157/7 162/20 171/1 171/4
shouldn't [1] 96/17
show [10] 33/25 42/3 61/4 61/14 63/8 70/20 148/15 154/7 163/8 169/24
showed [7] 29/17 96/2 101/6 127/12 145/20 155/19 157/2
showing [3] 60/12 117/1 118/13
shown [6] 12/5 47/5 62/21 71/8 100/17 106/13
shows [5] 18/24 79/17 100/3 135/10 161/22
side [1] 103/16
significance [2] 132/20 133/8
significant [9] 2/18 2/20 54/18 110/25 152/25 154/5 155/19 156/1 157/3
signs [2] 60/12 80/10
silence [1] 82/12
similar [5] 15/25 27/4 49/12 62/20 101/17
simple [1] 10/14
simply [2] 2/21 94/17
since [20] 8/23 11/4 12/14 17/5 20/15 24/6 25/5 37/6 37/24 54/21 90/18 100/22 111/21 127/13 128/4 128/13 143/4 143/7 154/16 166/6
sincerely [1] 23/3
single [3] 51/20 52/18 154/17
Sinoussi [2] 161/25 163/8
sir [91] 1/4 5/13 6/1 9/11 15/20 17/19 18/11 18/17 18/22 23/10 24/25 25/16 26/9 28/25 31/2 34/1

S

sir... [75] 34/21 36/7 38/1 38/15 42/1 42/5 42/9 42/15 43/4 45/7 53/4 54/25 57/22 58/12 59/8 59/9 62/10 62/12 63/14 68/1 68/25 69/15 71/22 73/9 75/6 76/11 78/12 85/1 86/12 87/23 91/19 94/23 94/25 95/25 97/2 97/23 99/16 99/24 101/9 110/19 115/14 117/19 120/7 121/19 122/19 123/5 126/18 130/9 131/12 132/9 132/21 134/2 136/25 137/4 137/25 138/9 139/15 140/25 147/16 147/24 148/6 151/11 153/12 156/5 157/6 159/25 160/17 160/25 161/19 164/11 165/2 165/19 168/3 170/4 172/7
Sir George Godber [1] 43/4
Sir Philip Rogers [1] 45/7
situation [6] 50/19 73/18 84/6 84/8 104/8 129/16
situations [1] 62/20
six [10] 9/3 34/8 49/25 55/17 73/14 81/4 96/18 97/6 108/11 132/16
six months [1] 96/18
six-month [1] 34/8
sixth [1] 152/15
size [2] 47/17 101/11
sizes [7] 11/9 11/16 38/12 47/1 62/14 63/6 101/13
skip [3] 12/18 13/5 50/6
slightly [3] 15/23 36/3 97/2
slowed [1] 159/20
small [15] 8/2 14/21 16/18 23/22 34/7 42/2 51/17 52/15 72/1 72/5 91/3 108/9 110/2 117/23 124/21
smaller [3] 6/12 47/16 167/7
Smith [4] 5/12 5/14 127/23 128/11
Smithies [1] 113/16
SNBTS [4] 102/23 103/1 103/5 103/11
so [167] 1/10 1/15 2/3 2/18 4/15 7/4 7/12 8/8 8/14 9/10 10/5 11/8 12/1 13/12 14/17 15/23 18/11 18/20 19/1 19/8 19/24 21/2 21/10 22/2 23/23 23/24 24/3 25/16 26/19 28/12 29/9 30/11 31/12 33/7 34/4 35/7 36/7 36/15 37/7 37/21 38/1 39/10 40/12 44/24 45/12 45/22 46/24 47/21 47/25 49/8 52/15 52/25 53/18 54/16 55/17 56/10 59/14 61/13 62/3 63/2 64/1 64/2 64/23 64/23 65/5 65/20 66/21 67/7 67/17 67/23 68/25 70/10 72/2 73/21 77/21 78/12 78/17 80/9 80/24 81/11 84/12 84/15 85/15 86/3 87/4 87/23 89/14 90/3 91/5 91/19 94/8 94/13 94/15 95/24 97/4 97/13 97/20 98/12 98/15 98/21 99/16 100/7 101/13 101/24 102/6 102/24 103/9 103/18 105/25 107/18 108/10 109/8 115/14 117/15 117/16 117/17 117/24 118/19 120/2 122/16 123/23 126/18 127/7 128/3 128/5 129/9 129/17 130/7 132/17 132/19 133/7 133/19 134/2 135/1 136/6 136/9 136/23 137/4 139/14 139/21 140/20 141/10 142/12 144/8 145/3 145/8 149/12 150/19 152/21 154/7 157/6 157/19 158/12 159/25 160/9 161/19 162/5 163/10 163/21 167/16 167/24 168/22 169/6 170/20 171/1 171/6 172/13
social [5] 8/21 9/2 30/16 129/14 140/6
society [7] 4/2 9/9 76/13 76/21 124/15 150/23 151/8
Society's [2] 150/24 150/25
soluble [1] 30/9
solution [1] 57/16
solved [1] 59/4
some [76] 1/20 1/20 1/24 2/5 3/20 4/25 5/24 6/8 9/12 9/20 15/24 18/21 23/20 24/2 24/21 25/1 25/20 29/8 31/10 34/13 36/7 36/19 45/14 58/2 59/24 61/1 61/11 62/19 63/19 63/24 65/3 67/8 69/25 69/25 74/4 74/11 74/12 74/21 78/18 79/12 83/21 85/20 86/9 92/2 98/15 103/13 103/14 103/18 108/2 110/5 112/20 114/11 115/12 121/9 124/5 126/1 131/19 136/12 136/17 136/18 138/6 139/24 141/3 142/13 143/7 146/7 147/23 151/2 152/22 152/24 153/7 153/13 154/8 161/23 163/10 170/12
someone [6] 41/22 108/4 120/20 127/4 127/9 147/23
something [5] 40/14 48/7 70/22 73/12 98/24
sometimes [2] 3/19 49/20
somewhere [1] 48/20
soon [4] 45/9 89/7 107/12 138/20
sooner [1] 113/23
sorry [12] 11/24 19/5 26/6 37/18 85/21 86/24 87/14 97/2 113/18 136/5 139/19 162/4
sought [3] 144/8 145/19 171/16
sound [1] 154/24
source [3] 7/18 16/1 126/8
sources [9] 17/7 45/11 59/1 59/5 78/10 110/8 110/9 112/17 126/11
speaking [1] 1/6
special [3] 71/19 71/25 154/6
specialise [1] 6/19
specialised [2] 8/18 8/24
specialist [3] 5/11 5/12 136/20
specially [1] 104/24
specific [7] 6/6 60/15 60/25 60/25 61/19 79/14 83/1
specifically [3] 76/23 133/19 172/2
specimens [4] 81/4 81/7 82/4 82/6
speculate [1] 82/15
speculation [1] 158/12
spelling [2] 34/24 34/25
spelt [3] 34/23 34/24 38/9
spend [1] 59/13
spending [1] 19/21
spent [2] 19/12 57/9
Spero [1] 156/4
Speywood [4] 34/20 35/1 35/4 35/22
spite [1] 158/4
spoken [1] 108/6
Spooner [11] 5/4 65/19 86/5 116/2 116/18 118/10 121/4 146/7 146/17 146/23 147/7
spouses [5] 130/13 130/18 131/2 150/13 150/14
spread [1] 166/19
spreads [1] 134/15
St [4] 33/12 33/17 33/21 55/22
St Thomas' [3] 33/12 33/21 55/22
staff [5] 8/21 52/7 108/24 146/9 146/16
stage [20] 5/7 13/15 14/20 18/15 21/25 41/25 47/13 47/16 47/19 54/16 54/23 57/22 61/2 78/19 107/20 149/8 150/23 154/6 160/11 160/14
standards [1] 52/15
standing [2] 146/8 150/22
stands [1] 21/20
start [6] 6/11 10/5 32/18 64/1 107/19 113/21
started [1] 14/7
starting [2] 40/20 74/2
state [10] 24/20 32/11 44/5 44/6 58/15 64/10 123/13 123/16 123/17 170/15
stated [4] 29/8 59/17 154/15 169/17
statement [10] 5/14 5/19 71/13 126/3 126/7 157/19 160/7 160/15 160/21 167/24
statements [9] 138/3 151/13 151/19 151/25 152/4 152/22 153/10 170/10 170/11
states [9] 13/17 40/2 40/6 40/24 41/1 64/17 64/23 148/10 163/2
statistical [2] 146/11 147/4
statistics [1] 16/1
status [5] 116/6 118/2 120/4 124/24 144/19
statutory [1] 125/16
stay [1] 172/24
steadily [2] 12/8 12/15
steady [1] 13/7
stems [1] 138/18
steps [4] 41/14 79/19 156/18 170/24
sticking [1] 55/1
stigma [2] 138/12 145/6
still [15] 12/10 32/9 56/25 82/22 83/3 85/8 85/16 93/8 104/14 110/2 110/25 112/12 115/6 141/6 161/22
stimulated [1] 163/18
stir [1] 64/22
stirred [1] 65/4
stock [3] 108/9 110/3 112/14
Stockholm [1] 75/2
stocks [2] 29/11 57/17
stop [5] 99/17 129/25 164/21 164/23 164/25
storage [2] 51/19 143/1
store [2] 21/22 137/22
stored [5] 32/10 98/15 98/16 127/12 127/15
stores [1] 57/18
strategic [1] 139/9
streamlined [1] 9/1
strenuous [1] 38/17
stress [3] 129/7 140/17 159/14
stressed [1] 8/16
strict [1] 119/18
strikingly [1] 83/4
striven [1] 24/8
strong [3] 29/3 158/22 162/12
strongly [4] 90/20 114/15 114/16 122/13
structure [1] 149/19
studies [23] 4/12 5/24 47/4 60/24 60/25 61/2 61/19 88/20 89/17 90/20 98/22 100/15 101/17 102/12 102/22 102/24 103/6 103/18 149/22 149/25 155/25 157/1 171/23
study [46] 3/14 4/13 60/15 60/19 60/25 62/2 62/5 64/5 64/13 81/19 81/20 82/9 82/22 83/16 83/22 89/3 91/2 92/8 95/14 95/15 95/25 97/17 97/20 98/20 99/15 100/2 100/10 101/3 101/5 102/4 102/11 123/13 123/15 123/23 128/5 128/6 130/5 130/6 141/21 148/10 148/11 148/14 148/17 149/2 155/24 156/18
sub [1] 80/9
sub-set [1] 80/9
subcommittee [2] 3/22 150/6
subcommittees [1] 3/21
subject [4] 64/4 68/16 87/4 152/13
Subjects [1] 96/24
submit [2] 99/15 117/22
submitted [3] 5/8 5/8 118/2
subset [1] 81/24
subsets [1] 80/14
substances [1] 23/8
substantial [1] 112/12
substantially [1] 13/22
successful [1] 8/17
successfully [1] 7/19
such [12] 62/21 69/12 76/21 102/24 122/20 125/2 125/21 140/13 158/22 159/4 167/1 167/23
suffering [2] 98/5 130/3
sufficiency [8] 30/11 38/17 38/18 41/15 41/25 45/16 48/3 58/11
sufficient [8] 40/15 57/5 152/18 163/19 163/22 166/1 171/1 171/23
suggest [7] 15/14 53/13 71/5 75/21 75/24 128/15 148/25
suggested [8] 20/23 37/20 45/6 69/18 71/6 134/18 136/17 171/25
suggesting [1] 66/24

S

suggestion [7] 52/23 66/1 69/21 70/13 74/23 75/18 145/5
suggestions [1] 106/5
suggests [4] 4/6 79/5 132/12 160/9
suicide [1] 125/1
suitability [1] 171/10
suitable [8] 17/6 33/1 91/6 94/6 94/12 94/19 106/2 159/7
sum [2] 19/14 57/7
summary [2] 128/3 129/10
super [1] 2/10
superior [1] 10/15
supplement [2] 56/13 57/5
supplemented [2] 16/17 18/1
supplied [4] 16/15 16/17 112/18 128/2
supplies [8] 25/21 29/13 44/19 58/11 108/17 108/24 109/10 166/2
supply [46] 6/13 6/18 6/20 8/1 16/6 16/22 17/8 17/24 17/25 18/4 20/2 20/8 20/10 20/21 21/12 25/6 25/22 26/15 26/18 28/3 28/13 29/7 29/8 29/14 30/2 30/9 30/18 37/11 38/5 39/9 39/23 42/17 42/18 43/13 44/3 44/5 44/6 50/8 50/17 50/22 55/25 57/4 59/23 102/6 108/21 166/4
support [5] 27/15 66/16 68/17 102/21 123/2
supporter [1] 29/3
suppose [2] 70/20 71/10
suppressed [1] 70/3
suppressor [1] 67/13
supra [1] 22/20
sure [11] 16/8 21/13 37/21 48/9 49/12 53/7 58/2 77/23 92/3 103/16 138/20
Surely [1] 41/6
surgeons [1] 8/20
surgery [3] 7/20 8/3 18/10
surgical [2] 24/19 91/12
surveillance [8] 67/23 71/9 77/17 77/20 100/16 144/14 156/19 164/10
survey [9] 48/14 67/8 116/3 116/21 117/8 117/12 118/7 118/20 144/4
surveys [3] 118/11 119/23 145/19
susceptible [2] 95/13 102/8
suspect [2] 172/3 172/6
suspected [1] 145/17
suspended [1] 106/12
switch [8] 9/18 37/7 38/7 160/20 164/21 165/24 166/9 167/13
switching [2] 159/13 168/5
sympathy [1] 122/12
Symposium [1] 6/25
symptoms [2] 69/4 144/19
syndrome [2] 65/24 68/6
system [4] 69/12 69/23 143/9 164/9

T

T helper [1] 67/13
table [5] 10/8 10/9 11/21 15/25 34/1
Table V [1] 10/8
tables [4] 14/23 14/25 15/5 15/23
take [10] 38/25 42/10 57/21 71/15 76/18 109/25 127/17 141/1 170/25 172/25
taken [7] 41/15 42/20 54/24 76/19 79/19 121/16 140/10
takeover [1] 59/11
takes [1] 71/20
taking [3] 30/19 43/6 129/24
talk [8] 26/14 37/16 39/23 51/4 53/23 113/10 138/9 168/9
talking [4] 31/12 31/13 36/20 71/10
talks [11] 7/21 32/16 47/1 52/9 57/11 61/17 63/1 85/10 86/1 93/14 169/20
task [2] 3/24 66/13
taxpayer [1] 23/14
teachers [1] 8/22
technician [1] 81/3
Tedder [3] 130/11 130/14 130/24
telephone [6] 64/16 80/12 81/19 124/12 140/2 146/18
telephoning [1] 82/10
tell [1] 132/10
telling [1] 14/17
tells [2] 95/24 147/5
temporarily [2] 129/25 172/16
ten [4] 62/22 66/3 97/12 169/15
tend [2] 35/23 71/5
tendency [1] 10/20
tension [1] 132/17
tenth [1] 44/2
term [7] 30/8 51/10 61/10 134/10 155/13 157/1 159/12
terms [26] 2/11 2/25 14/18 16/6 19/1 36/12 38/12 38/16 43/5 45/17 46/25 61/19 63/4 67/21 85/17 91/20 106/20 109/3 115/14 125/6 141/22 149/5 150/5 150/5 152/7 166/23
test [24] 47/2 70/9 80/18 83/1 117/5 117/5 118/17 118/17 119/2 119/3 119/4 119/5 127/21 127/25 128/2 128/12 129/11 132/6 132/18 132/23 135/17 136/3 152/25 171/17
tested [26] 17/15 53/22 88/16 98/3 113/22 113/24 114/2 114/7 114/16 115/20 116/15 117/4 118/16 118/24 120/11 120/17 121/13 122/14 127/10 127/16 132/14 134/9 134/20 135/13 152/9 171/16
testing [21] 80/9 98/9 115/23 122/6 122/16 122/20 123/3 123/22 126/17 128/9 128/19 128/24 129/1 131/20 131/22 132/12 133/6 135/11 136/24 159/24 171/14
tests [19] 61/22 61/23 68/23 69/7 78/3 78/16 98/2 98/11 99/3 102/6 127/11 128/16 128/20 131/7 133/8 136/22 152/23 155/21 156/1
text [1] 111/8
than [46] 3/15 6/12 10/21 11/5 11/7 12/6 12/13 13/1 13/20 14/5 20/15 22/23 23/2 29/19 36/3 40/7 44/16 47/7 50/20 51/16 51/21 52/18 52/21 53/1 57/13 62/23 67/14 70/21 71/9 72/14 82/15 84/22 97/8 101/13 106/18 114/15 114/23 115/11 137/23 139/5 154/18 158/18 162/22 166/15 167/6 168/2
than patients [1] 67/14
thank [19] 11/20 11/25 12/19 24/4 36/22 42/8 48/12 77/10 92/7 97/1 111/8 113/18 134/2 136/11 149/17 172/9 173/1 173/1 173/4
thanks [3] 90/15 136/8 173/2
that [604]
that's [54] 2/9 10/5 23/24 25/7 26/13 30/4 33/3 34/4 35/2 35/2 35/7 35/10 38/12 38/15 48/23 52/25 54/20 54/25 56/10 59/12 63/15 67/12 67/21 68/1 72/17 75/11 75/18 85/21 87/4 90/3 93/15 94/24 95/24 97/10 99/13 101/24 105/5 113/12 133/7 133/19 133/25 135/8 135/25 136/20 136/23 142/20 148/23 156/11 160/3 161/16 162/3 163/11 168/22 169/6
their [44] 9/10 9/13 18/4 23/21 39/11 44/6 68/21 69/19 89/15 90/20 91/20 94/17 95/22 97/18 97/18 98/22 106/1 117/13 118/1 118/2 118/2 118/22 119/24 130/17 131/22 132/1 132/5 132/20 133/18 134/25 135/14 138/4 138/7 145/25 151/14 152/1 152/1 152/13 152/23 153/10 161/12 167/22 168/1 171/16
them [22] 3/10 35/18 40/14 49/10 56/12 57/19 86/11 88/17 97/18 99/15 119/14 135/1 136/19 137/22 137/23 152/2 153/7 153/21 166/11 168/6 171/18 171/24
theme [12] 19/17 102/12 132/23 132/24 151/24 152/3 152/8 152/11 152/15 152/18 153/2 161/18
themes [3] 151/12 151/16 151/19
themselves [2] 148/25 161/12
then [244]
then -- so [1] 19/1
theoretically [1] 52/19
theory [1] 46/20
therapeutic [13] 7/5 10/2 10/3 12/3 17/5 17/24 29/13 43/13 48/17 50/3 53/25 57/17 143/18
therapy [24] 13/17 13/20 13/22 13/25 14/2 14/4 14/8 14/11 14/14 14/20 21/2 24/21 26/19 26/22 27/8 28/11 28/16 29/4 29/6 32/19 74/15 93/21 114/14 159/7
there [200]
there's [59] 10/20 19/2 20/11 25/16 26/18 28/2 28/20 29/13 30/15 31/9 45/12 46/12 49/9 50/23 51/2 51/13 53/24 54/7 72/7 72/12 74/4 74/6 77/11 80/1 81/15 82/16 84/9 84/9 84/18 84/20 84/23 85/4 85/6 85/13 87/17 89/12 92/2 98/8 102/13 107/23 110/18 122/8 134/18 135/2 135/20 135/23 139/3 139/13 141/22 142/12 144/9 144/10 144/14 145/4 147/14 149/20 153/24 155/4 162/9
thereabouts [1] 135/25
Thereafter [1] 37/2
therefore [18] 18/4 36/4 36/5 46/20 63/3 70/2 80/17 88/20 89/22 105/18 112/25 113/25 122/18 131/9 131/13 137/16 140/14 140/15
these [60] 9/5 15/4 17/11 22/6 22/12 27/9 27/16 28/14 35/5 35/5 35/15 36/8 39/3 39/8 39/11 39/20 39/25 40/5 41/7 41/11 43/4 44/14 45/8 56/8 66/11 71/25 72/23 81/9 85/20 86/9 87/7 87/18 87/21 89/3 89/24 93/17 93/20 94/13 95/6 97/14 100/20 101/10 101/16 102/2 102/3 104/17 105/22 112/7 113/1 120/12 120/15 125/12 125/19 128/16 132/17 136/2 136/22 137/17 140/17 151/19
Thetford [1] 35/6
they [46] 22/23 27/3 28/3 28/4 35/11 35/13 35/19 39/9 39/10 39/17 51/4 54/17 56/12 60/2 71/1 72/25 75/3 82/18 83/8 89/20 89/24 92/20 93/11 96/17 105/18 105/20 108/16 112/19 113/3 113/7 113/9 116/9 116/10 119/15 124/19 131/7 131/23 132/13 132/24 135/14 137/18 139/6 152/12 156/21 170/25 171/15
thing [2] 32/6 65/2
things [5] 31/11 47/23 56/7 93/8 97/5
think [60] 8/4 9/24 18/23 32/5 32/24 33/23 35/25 38/24 41/23 42/4 45/3 45/13 47/10 48/22 48/24 49/13 49/24 54/9 54/20 58/6 60/2 60/7 68/21 69/6 70/16 73/17 73/18 74/17 75/22 76/18 76/24 77/22 80/14 81/8 82/22 85/1 86/10 90/22 91/3 91/8 91/13 96/21 99/18 116/25 125/15 132/13 133/25 136/4 136/16 137/3 137/17 145/3 145/5 145/14 151/17 155/11 159/1 163/5 169/23 170/4
thinking [1] 89/18
thinks [1] 75/9
third [9] 26/6 36/1 52/11 55/7 56/10 66/19 74/6 84/5 152/3
thirteen [2] 44/4

T

thirteen... [1] 117/14
thirty [3] 9/3 114/23 120/11
thirty-six [1] 9/3
this [342]
Thomas' [4] 33/12 33/17 33/21 55/22
those [52] 3/6 6/8 7/12 9/10 17/21 26/2 27/4 33/15 37/14 54/16 64/3 70/4 78/10 85/18 87/16 88/23 89/1 89/18 91/11 93/17 98/16 98/21 100/18 105/16 106/7 111/19 113/8 117/3 118/15 119/15 122/4 129/8 129/9 129/19 130/8 133/9 136/18 141/19 143/6 143/20 144/1 144/9 149/6 152/25 157/15 162/22 169/23 171/19 172/19 172/22 172/24 173/2
though [4] 49/2 53/10 119/12 153/5
thought [3] 28/3 156/25 163/19
thoughts [1] 131/19
thousands [1] 51/19
threat [1] 3/2
three [12] 12/18 56/9 66/17 90/18 90/19 93/1 107/1 120/11 129/23 129/24 164/20 167/13
Thrombosis [2] 3/23 4/1
through [16] 14/23 20/7 50/16 57/21 58/20 83/23 85/8 109/4 110/21 116/12 122/4 128/25 136/20 150/15 151/1 153/24
throughout [6] 19/17 59/15 60/12 79/25 143/25 161/4
thrown [1] 153/6
Thursday [1] 172/19
thus [4] 13/21 14/2 17/16 168/3
till [1] 12/18
time [50] 1/5 2/25 4/5 9/10 9/13 11/18 15/18 18/13 19/22 24/18 25/23 31/22 36/9 37/2 41/11 46/5 49/6 49/21 54/17 56/14 57/19 58/2 58/6 59/10 60/25 62/17 63/12 80/2 80/4 80/6 84/12 96/1 99/16 100/20 101/8 103/20 110/2 114/23 116/14 126/1 127/20 132/19 133/4 147/9 157/4 161/24 166/19 168/14 168/19 170/17
time-frame [2] 1/5 4/5
times [4] 22/22 62/22 157/8 162/5
timing [1] 123/5
title [2] 5/9 121/5
to [1129]
today [9] 1/4 1/21 2/3 61/2 127/6 137/8 141/11 149/7 153/22
today's [5] 31/6 45/21 72/22 77/1 170/4
told [17] 6/24 20/13 76/1 78/13 88/7 98/1 98/18 104/6 104/19 117/25 118/9 125/13 132/6 134/8 134/21 134/25 171/15
too [2] 28/8 73/23
took [5] 1/9 4/24 42/17 151/9 156/18
top [8] 12/19 47/1 50/25 87/14 147/4 158/15 165/11 167/11
topic [3] 58/10 137/2 137/5
topics [1] 30/6
total [6] 15/2 29/23 78/5 116/14 129/19 143/17
touch [1] 90/19
towards [11] 6/7 7/3 13/16 32/15 36/12 61/13 62/12 66/22 111/7 145/20 154/23
town [1] 144/3
traced [1] 84/15
transaminases [1] 106/14
transfer [1] 25/12
transferred [1] 107/11
transfused [4] 78/8 115/3 115/4 168/12
transfusion [49] 4/4 4/8 7/18 10/15 12/10 12/23 16/15 25/6 25/7 26/10 31/14 31/21 31/23 43/21 46/22 49/8 49/17 50/14 51/8 52/6 59/4 59/7 62/24 74/3 87/2 90/10 95/8 95/22 96/4 100/24 101/2 102/17 107/7 110/10 113/9 122/9 125/12 125/14 130/1 133/7 133/14 140/6 150/15 156/17 157/22 159/14 159/16 167/9 167/15
transfusions [5] 66/18 66/25 67/4 100/21 157/17
transmissible [2] 70/14 162/13
transmission [15] 92/23 93/4 105/19 115/1 128/15 130/21 131/1 131/4 131/14 134/16 140/24 146/16 150/8 150/10 154/14
transmit [4] 62/22 115/6 132/5 154/18
transmitted [2] 110/11 120/9
transmitting [5] 69/10 88/12 114/17 130/17 159/22
transport [3] 139/25 140/4 140/23
transported [2] 140/12 140/19
transporting [1] 140/22
Travenol [2] 34/18 104/21
treasurer [4] 106/23 108/5 109/6 109/8
treasurer's [1] 107/22
treat [8] 10/7 16/23 17/11 39/25 54/15 55/9 143/18 167/3
treated [58] 9/6 17/2 47/6 52/20 57/1 67/11 69/18 69/22 69/24 75/4 75/14 80/16 81/9 81/22 81/22 86/8 90/9 92/22 96/16 96/17 101/7 102/23 103/6 103/12 103/14 103/24 106/7 106/18 106/21 107/10 107/19 107/24 108/9 108/13 108/16 108/21 108/23 109/14 109/17 110/4 110/7 111/1 111/3 111/24 112/2 112/4 112/15 113/5 115/16 117/2 118/14 140/17 151/13 152/22 156/20 163/18 163/22 169/14
treating [3] 2/12 2/20 152/2
treatment [112] 1/11 2/7 2/11 2/19 3/1 3/5 3/17 7/4 7/6 8/2 9/4 9/15 9/23 10/16 14/2 17/22 18/3 22/19 23/19 24/24 24/25 27/8 27/10 27/10 27/11 27/12 28/9 28/19 28/21 30/1 30/24 31/18 31/25 32/6 32/12 33/2 33/3 33/6 33/9 33/11 33/18 33/25 34/4 34/6 34/8 36/23 39/2 39/11 39/16 39/17 40/18 43/17 44/9 44/10 45/5 45/20 45/24 50/11 51/12 52/11 53/9 53/9 54/1 56/1 56/6 58/24 59/20 60/17 62/10 69/1 69/12 69/19 69/23 74/16 80/19 80/21 82/3 82/20 85/17 88/14 88/24 90/14 91/4 91/8 93/5 93/18 95/19 106/4 107/12 110/16 111/16 112/8 129/21 129/25 134/12 137/12 138/7 139/16 142/7 142/17 151/22 153/11 154/6 159/5 159/8 164/25 165/14 166/16 167/22 168/1 171/9 171/19
treatments [3] 4/14 11/22 142/20
Treloar [3] 27/1 28/15 28/17
Treloars [5] 27/15 27/18 62/3 62/5 62/6
trial [24] 26/18 26/22 26/24 27/4 27/6 27/15 28/10 28/15 33/11 33/12 33/18 33/20 87/9 90/1 94/13 94/20 96/9 96/19 97/5 97/7 104/10 106/2 106/11 128/14
trials [19] 87/18 89/24 90/2 90/8 93/13 93/16 94/3 94/9 94/18 95/1 96/12 99/25 102/7 103/23 104/4 104/10 104/17 121/2 149/5
trigger [1] 90/5
Trillwood [1] 16/9
trouble [1] 26/21
Trowell [4] 5/15 65/19 95/16 133/10
true [1] 38/15
trust [4] 23/15 123/12 136/2 152/1
try [9] 41/11 41/12 41/13 69/3 70/11 75/1 78/10 91/16 116/10
trying [3] 26/21 49/23 53/4
Tuddenham [1] 172/18
Tuesday [6] 81/4 172/14 172/15 172/17 173/5 173/8
turn [7] 10/9 25/24 82/19 83/12 122/5 139/18 151/11
turned [1] 139/4
Turning [1] 121/19
turns [1] 170/1
twenty [1] 66/19
twice [1] 25/9
two [30] 2/19 3/6 11/24 15/23 17/7 27/10 30/6 40/4 46/6 47/25 53/16 56/6 57/23 60/16 64/3 64/20 66/18 71/6 75/6 78/12 91/6 93/1 106/12 108/19 110/10 123/25 155/5 162/1 164/11 167/13
twofold [1] 59/18
type [6] 36/23 38/14 48/17 54/14 72/8 143/10
types [2] 10/1 10/3

U

UK [53] 2/16 2/17 9/23 13/3 13/4 18/16 43/8 56/20 58/4 59/5 62/10 62/17 77/17 78/1 78/6 78/14 93/21 104/2 107/4 108/17 111/12 111/21 112/1 112/13 112/18 112/24 116/4 116/7 116/22 116/23 118/8 118/12 121/6 121/8 121/11 129/8 142/2 142/9 142/25 150/8 150/17 156/12 156/16 158/4 158/4 158/25 159/3 160/16 162/16 162/17 163/25 164/6 164/10
UK Factor VIII [1] 112/13
UK plasma [1] 112/1
UKHCDO [15] 3/18 3/19 3/21 4/9 4/16 60/2 61/8 64/3 73/11 141/20 149/10 160/10 169/2 171/4 171/4
UKHCDO's [3] 5/23 44/24 65/14
ultimate [1] 93/3
ultimately [2] 37/13 115/9
unable [2] 21/16 108/13
unacceptable [2] 165/6 165/18
unanswered [1] 163/21
unavoidable [1] 17/5
uncertainties [1] 131/5
uncertainty [4] 132/9 161/22 162/7 169/18
unclear [2] 87/17 151/10
uncommon [1] 155/17
uncontrolled [1] 165/9
under [25] 1/11 2/24 2/24 4/20 4/22 8/11 10/1 29/12 34/3 79/9 84/5 87/13 87/19 88/4 96/23 96/24 97/19 98/8 101/22 122/5 125/25 130/8 146/3 156/14 157/24
underestimate [1] 170/19
undergone [1] 24/18
underlining [1] 79/1
underspending [1] 22/24
understand [8] 18/16 18/17 20/8 88/2 93/1 108/18 124/16 150/21
understanding [5] 9/12 11/17 63/3 79/23 125/24
understating [1] 79/6
understood [1] 20/4
undertake [2] 67/7 94/22
undertaken [21] 1/22 5/24 14/24 27/6 33/12 77/22 95/15 97/25 98/2 98/22 100/4 102/25 103/19 103/23 117/20 128/19 128/24 141/4 141/6 141/16 171/23
undertaking [3] 94/19 101/16 148/18
undertreatment [1] 57/14
undesirable [2] 89/10 89/16
undoubtedly [1] 40/25
undue [1] 103/16
unethical [2] 18/2 56/8
Unfortunately [1] 154/21
unheated [5] 111/13 112/12 112/17 112/24 169/21

F:

U

unique [2] 3/7 128/17
unit [7] 4/19 35/20 44/16 121/2 125/25 129/14 143/10
United [9] 9/4 17/4 35/13 40/2 40/6 40/24 41/1 87/8 154/2
United Kingdom [4] 9/4 17/4 87/8 154/2
United Kingdom-based [1] 35/13
United States [4] 40/2 40/6 40/24 41/1
units [10] 14/8 14/15 29/23 29/25 34/3 35/24 36/1 56/15 97/8 167/2
universal [1] 54/8
University [1] 121/2
unknown [1] 158/3
unless [5] 40/10 40/14 99/8 105/22 126/5
unlikely [2] 29/18 88/18
unnatural [2] 125/7 125/11
unnecessary [1] 56/8
unpaid [1] 62/23
unpleasant [1] 22/7
unreasonable [3] 20/17 159/10 160/23
unreliable [1] 135/16
unresolved [1] 22/12
unsuitable [1] 166/15
unsurprisingly [3] 60/1 60/10 61/18
untested [6] 114/2 114/3 114/10 114/14 114/21 115/8
until [15] 4/23 4/24 7/23 17/4 37/1 37/3 55/10 58/6 85/5 107/25 114/22 143/6 159/23 173/4 173/8
untoward [1] 109/5
untransfused [3] 90/23 91/4 103/7
untreated [5] 96/9 102/13 108/18 111/22 168/20
up [50] 5/1 15/7 20/14 22/13 23/12 25/22 27/21 30/5 30/17 36/13 37/17 42/25 43/12 50/15 52/3 52/11 56/3 57/18 64/6 65/4 67/15 68/18 68/22 69/7 70/8 71/15 78/9 79/11 79/20 83/9 84/12 93/8 93/15 94/5 98/1 99/2 99/13 105/25 106/22 116/20 127/3 127/17 134/10 136/6 141/14 147/20 153/6 155/18 164/9 164/9
up-to-date [1] 164/9
update [7] 75/13 76/15 76/20 85/14 104/5 106/8 144/12
updated [1] 85/16
updating [2] 84/8 103/22
upon [12] 11/17 16/14 18/24 22/8 23/18 47/10 48/22 60/20 82/5 83/21 150/19 172/20
upshot [1] 28/13
urgency [1] 70/7
urgent [3] 30/3 44/18 71/7
urgently [3] 28/8 65/2 65/9
urges [1] 109/6
urging [1] 48/1
us [27] 14/17 18/2 19/15 20/17 22/1 22/2 24/2 33/1 34/22 35/1 36/7 36/19 41/6 42/7 51/25 62/20 65/5 69/14 70/1 70/4 70/21 71/10 89/15 92/16 95/24 137/15 160/16
US concentrates [2] 69/14 70/1
USA [6] 44/12 105/18 158/25 159/2 162/16 164/6
usage [9] 13/12 15/17 20/22 25/17 34/2 35/15 36/8 36/20 115/15
use [75] 3/14 3/25 8/10 9/5 10/20 14/18 15/1 15/3 15/9 18/1 18/7 18/12 21/21 23/2 23/16 24/8 25/20 26/9 26/12 27/24 28/14 29/2 29/3 33/20 33/21 35/23 36/12 37/15 39/11 41/19 44/1 44/15 51/15 55/6 55/12 56/16 56/18 56/21 56/22 59/15 67/25 69/11 72/13 75/3 75/14 84/18 87/20 89/15 90/22 92/1 92/24 93/16 94/5 98/11 103/5 106/17 106/21 107/16 107/24 108/15 108/23 110/3 111/3 111/22 113/4 114/8 115/8 115/8 115/11 115/15 128/17 162/20 164/24 169/14 170/23
used [62] 7/14 7/19 10/2 10/3 10/13 10/19 12/3 12/7 12/11 12/14 12/16 12/21 13/1 13/4 13/8 13/9 14/3 14/3 14/8 14/12 14/15 15/3 15/15 17/12 18/8 26/14 27/20 27/23 28/15 31/25 32/24 33/4 33/24 34/6 35/17 48/17 49/4 52/22 54/4 54/14 59/23 62/17 72/8 87/8 89/8 98/20 104/18 115/17 117/7 127/6 128/4 128/10 130/2 130/4 141/20 142/8 142/16 143/18 143/24 144/14 146/12 166/6
useful [5] 7/18 32/11 122/18 136/17 154/8
using [30] 24/12 28/22 28/24 29/6 32/18 47/8 47/16 54/16 69/9 72/16 75/4 104/12 107/19 111/1 112/11 112/12 112/15 114/21 115/2 115/19 143/8 159/3 159/15 164/18 164/21 164/23 167/2 168/10 168/17 168/23
usual [2] 13/25 91/8
usually [1] 100/22

V

valid [1] 171/24
valuable [5] 12/25 13/10 56/21 81/8 82/12
value [1] 17/10
variability [1] 166/13
variable [2] 10/17 44/4
variation [1] 135/15
varies [1] 52/4
variety [1] 141/21
various [20] 4/13 7/25 11/22 15/5 20/3 20/6 24/19 50/2 51/23 82/25 88/22 99/12 106/5 106/7 133/20 143/16 144/1 148/11 160/19 173/3
vary [1] 43/22
very [55] 2/20 10/17 20/16 23/10 23/21 23/21 24/5 26/23 27/5 30/3 32/11 35/18 37/10 39/8 40/4 40/10 40/25 44/4 44/22 46/15 47/7 47/14 52/4 52/24 54/11 55/17 57/15 62/18 64/12 64/23 65/20 67/17 71/13 73/14 81/8 83/8 88/20 89/7 91/15 92/7 93/4 109/24 114/6 124/21 125/18 130/25 131/9 135/16 137/8 141/12 155/17 159/1 160/15 166/25 172/9
vetting [1] 64/25
victim [1] 125/25
Vienna [6] 17/9 27/25 74/24 75/19 76/2 76/6
Viennese [1] 76/22
view [21] 13/18 51/10 51/25 53/14 56/7 59/21 69/2 72/5 77/1 77/8 83/21 87/15 87/16 91/21 91/23 114/17 115/5 124/15 126/18 159/11 168/18
viewed [1] 9/13
views [3] 22/6 87/11 165/21
VIII [157] 3/22 7/19 7/24 10/12 10/25 13/2 13/4 13/8 13/8 13/11 14/3 14/9 14/15 15/3 15/6 18/5 20/3 20/9 21/12 21/15 21/20 21/22 22/17 22/21 23/2 23/16 24/6 24/12 24/15 24/16 25/10 25/13 25/13 25/15 25/18 25/20 29/16 30/7 30/19 30/20 34/3 34/14 34/16 35/20 36/23 37/1 37/10 37/14 37/15 38/6 39/7 43/19 44/19 48/15 50/3 50/8 50/20 50/22 53/14 54/13 55/8 55/13 56/1 56/5 56/11 56/15 56/17 57/1 57/2 57/5 58/7 58/25 59/19 62/16 63/2 63/5 64/24 66/10 67/5 69/9 69/11 69/13 69/22 74/3 74/14 74/16 75/11 78/7 81/10 81/13 84/11 84/16 87/3 88/10 89/4 90/14 90/18 93/14 93/18 93/21 95/2 95/5 95/18 95/23 96/8 96/17 98/19 99/25 100/12 100/24 101/7 101/11 101/19 102/23 103/6 103/14 104/4 104/12 104/16 104/24 105/2 105/17 106/4 108/10 108/14 108/16 108/18 109/14 109/24 110/1 111/1 111/22 111/25 112/13 113/24 114/11 142/6 142/7 154/12 154/15 154/18 154/25 156/23 159/17 162/20 163/16 163/19 164/18 164/22 165/25 166/3 166/14 166/15 167/3 168/10 169/21 169/22
viral [1] 92/23
virgin [1] 82/23
virologist [2] 131/18 158/10
virology [4] 133/5 135/6 135/10 136/7
virus [10] 52/18 54/6 70/15 99/6 128/15 134/15 140/7 159/20 162/14 163/8
virus-free [1] 159/20
viruses [4] 3/5 101/23 102/3 162/1
visit [2] 131/21 138/17
vital [1] 1/19
voluntary [1] 125/10
vomiting [1] 140/11
von [4] 90/24 129/2 129/6 144/11
von Willebrand's [4] 90/24 129/2 129/6 144/11

W

Waiter [4] 19/25 21/10 21/11 55/3
Wallace [2] 146/8 146/17
want [6] 23/10 27/6 86/7 140/25 149/16 151/11
wanted [4] 34/23 76/14 153/12 169/24
wants [1] 94/22
warrant [3] 72/7 72/12 163/20
was [246]
wasn't [2] 32/9 48/21
wastage [1] 25/2
wasteful [1] 29/18
Watt [4] 90/10 90/13 92/3 93/6
way [14] 8/22 35/9 61/9 70/23 79/21 87/6 88/23 102/1 102/9 109/13 140/18 143/11 157/1 173/5
ways [1] 3/7
we [442]
we'd [1] 34/23
we'll [12] 1/5 4/12 32/14 49/10 58/16 80/5 84/2 92/14 100/2 113/19 121/23 161/18
we're [8] 6/24 19/6 59/13 80/13 98/1 98/18 104/19 118/9
we've [25] 2/1 8/8 16/11 19/18 38/19 49/23 59/24 60/23 61/7 61/17 63/14 68/1 71/21 72/20 77/7 77/8 79/12 86/9 105/6 133/11 141/3 145/3 147/16 160/5 170/5
Wednesday [1] 172/17
week [14] 64/15 76/16 77/4 81/20 85/3 103/4 113/25 169/12 172/8 172/10 172/11 172/13 173/5 173/5
weeks [6] 32/15 70/9 90/11 90/20 98/2 108/11
weight [1] 82/3
Weiss [1] 163/5
welcome [1] 131/10
welfare [1] 8/23
well [18] 2/7 5/19 23/5 55/13 59/12 65/20 71/4 71/14 77/10 99/18 125/18 127/16 133/1 138/1 145/12 151/17 155/20 169/9
wellbeing [1] 24/9
Wellcome [2] 31/3 123/12
went [1] 157/4
were [110] 2/21 5/7 5/8 7/24 13/14 14/13 14/15 17/3 22/12 26/3 27/9 27/14 28/4 29/22 30/6 30/12 31/8 31/11 33/4 33/8 33/15 33/24 35/5 36/8 40/3 48/19 49/3 53/8 54/10 54/17 59/15 60/2 60/15 60/25 62/4 64/19 66/6 66/13 66/18 67/2 68/7 69/18 71/8 71/22 73/2 79/23 85/2 86/13 86/16 91/7 96/2 100/8 103/19 103/20 103/23 109/17 110/6 110/25

F:

W

were... [52] 111/3 112/9 112/10 112/11 112/12 112/15 116/24 117/6 117/21 117/25 118/21 120/6 120/8 120/11 120/12 120/13 120/14 120/15 120/16 120/18 121/15 123/25 127/11 127/15 127/16 141/4 141/8 142/16 143/7 145/24 148/16 152/5 155/20 155/23 157/14 158/5 160/10 162/1 162/19 162/22 164/8 165/3 166/14 167/21 167/25 168/1 169/8 170/25 171/14 171/15 171/15 171/16
West [1] 162/11
wet [1] 104/23
what [88] 2/1 3/18 4/5 10/10 13/17 31/2 32/13 33/19 34/24 35/2 35/14 48/19 53/3 54/21 58/8 61/14 63/23 64/17 69/23 69/24 70/10 70/16 70/25 72/17 75/25 76/9 76/22 77/23 78/19 79/6 80/5 80/13 82/14 83/13 83/15 85/19 88/21 90/25 91/22 97/21 103/15 104/19 106/20 113/19 119/1 119/3 120/24 122/23 130/20 130/25 131/6 131/8 131/13 131/13 131/25 132/10 132/19 133/21 134/3 134/7 136/21 139/13 141/7 141/8 141/9 142/16 148/9 148/15 155/7 156/7 156/14 157/7 158/19 161/3 161/14 162/6 163/21 164/13 164/14 165/11 170/14 170/24 171/2 171/3 171/6 171/7 171/14 172/5
what's [3] 59/2 71/2 78/24
when [46] 4/23 6/5 11/12 13/24 14/2 17/23 21/22 23/21 27/17 28/17 31/16 31/22 37/1 37/4 37/24 38/22 40/8 41/20 55/21 58/13 62/6 63/8 74/18 77/5 83/22 85/2 86/10 93/4 98/11 106/16 109/15 109/18 109/23 131/20 134/13 140/10 145/22 151/6 156/6 156/21 156/23 158/6 162/6 166/7 170/21 171/16
whenever [1] 27/11
where [27] 13/14 18/3 19/15 26/25 35/10 50/20 52/7 57/1 63/21 64/7 64/18 72/15 79/14 81/16 83/2 97/20 101/22 110/11 124/23 126/19 126/20 134/11 141/7 146/15 162/25 168/25 169/4
whereas [1] 112/17
whether [29] 1/13 11/16 27/7 27/13 53/4 57/2 75/1 76/3 79/20 87/15 89/8 98/24 102/1 102/20 110/2 110/3 115/19 117/25 120/7 127/14 128/13 132/18 142/5 142/6 145/13 145/24 162/1 165/2 167/9
which [99] 1/5 6/17 12/24 16/4 17/15 18/24 28/8 32/1 35/23 35/25 40/23 42/3 42/9 45/13 45/14 45/15 48/9 49/3 49/5 49/7 55/20 56/16 60/15 61/7 63/16 68/4 68/5 73/12 74/16 77/7 77/12 78/9 78/12 78/18 79/5 81/19 82/5 82/19 83/18 85/23 87/6 87/9 92/10 92/22 94/21 95/7 95/19 95/25 96/1 98/25 99/17 100/3 102/14 103/8 104/12 106/11 108/21 110/14 114/1 117/9 117/14 117/16 132/11 133/13 134/4 135/6 135/10 138/18 138/24 138/25 141/23 142/5 142/15 142/15 143/11 145/1 145/4 145/6 146/12 147/24 149/16 150/19 151/17 151/24 151/25 152/4 153/20 153/25 158/2 158/17 158/22 161/10 161/13 163/14 163/16 164/3 165/20 165/24 172/15
while [4] 23/22 43/10 44/5 140/15
whilst [2] 102/12 135/1
who [87] 1/8 2/21 4/22 5/2 5/4 5/12 5/15 5/21 8/22 14/1 14/7 16/8 20/9 24/17 24/18 31/5 33/15 34/12 37/15 40/18 41/22 46/21 47/6 55/9 64/11 66/4 68/23 69/17 72/1 73/2 80/16 80/18 81/12 81/14 82/23 84/10 84/11 88/24 91/4 93/17 93/21 94/20 95/20 98/21 100/21 102/4 104/7 104/16 106/1 106/3 107/8 113/8 117/1 117/4 118/13 118/16 120/5 120/14 121/11 121/13 122/12 124/2 127/5 127/8 127/10 129/23 130/16 138/3 138/6 139/20 140/10 140/11 143/22 148/13 150/13 151/18 153/5 153/9 153/10 155/20 158/10 171/21 172/19 172/22 172/24 173/2 173/3
who's [2] 92/4 96/16
whole [9] 7/7 32/3 57/4 60/5 64/21 65/2 66/17 112/5 113/18
wholeheartedly [1] 68/17
whom [8] 16/9 18/8 62/19 127/8 129/19 134/20 140/5 165/7
whose [6] 5/1 5/9 94/5 99/3 134/20 160/25
why [9] 26/13 48/18 56/25 69/16 84/23 135/9 135/25 160/19 170/20
wide [2] 77/20 108/7
widely [2] 156/24 166/19
wider [1] 106/18
widow [1] 153/5
wife [1] 135/19
will [130] 1/8 1/12 1/14 1/19 1/23 2/4 5/6 6/1 6/7 8/25 10/9 12/6 14/4 14/12 15/20 21/14 23/3 23/15 23/16 24/24 27/16 28/16 29/7 30/15 33/16 40/5 40/8 40/13 40/13 40/24 41/1 41/2 41/3 41/18 49/5 49/11 57/18 58/2 58/6 59/9 62/6 63/13 65/15 70/5 70/8 70/18 72/15 78/18 85/8 86/12 87/15 88/18 89/15 89/25 90/22 91/3 92/20 93/4 93/21 94/5 94/11 96/12 96/25 97/14 97/17 97/25 98/1 98/2 98/3 98/4 98/10 99/6 99/8 99/11 99/13 100/1 101/9 105/3 105/21 105/23 108/8 108/10 108/16 108/21 108/25 108/25 113/21 113/24 113/25 114/1 115/9 117/19 120/9 123/15 124/23 125/20 126/18 127/4 128/16 128/17 130/10 131/12 132/21 134/3 134/11 134/21 135/14 136/3 137/25 138/20 139/8 139/14 139/14 140/5 140/14 141/14 144/8 146/2 147/9 149/7 151/17 154/9 155/1 157/6 160/17 165/2 168/7 172/1 172/20 172/25
Willebrand's [4] 90/24 129/2 129/6 144/11
willing [2] 91/15 114/8
willingness [2] 110/15 139/15
Winter [1] 142/14
wish [17] 6/2 9/11 118/3 120/10 123/5 126/6 126/13 130/17 131/8 134/19 145/10 146/2 156/5 160/17 165/2 170/7 170/13
wished [1] 119/7
with [182]
withdrawn [2] 64/24 108/19
withhold [1] 18/3
withholding [1] 21/21
within [16] 19/7 19/7 19/19 23/4 23/24 40/4 59/5 60/2 70/9 94/2 108/2 121/19 122/17 129/13 134/24 150/17
without [17] 23/17 24/9 31/24 57/9 91/14 91/25 94/7 94/8 112/21 122/14 122/20 123/3 123/8 129/2 137/10 137/20 152/13
witness [4] 6/4 31/3 151/13 153/4
witnesses [3] 152/12 153/9 172/19
wives [2] 135/11 136/13
women [3] 120/11 120/15 136/22
won't [11] 2/3 14/23 19/18 57/21 59/8 68/3 106/8 116/12 127/3 153/16 154/7
wonder [2] 110/17 152/6
word [1] 79/1
words [3] 91/9 126/13 145/1
work [23] 1/10 1/21 2/3 4/19 7/15 15/12 40/23 41/12 62/4 74/8 100/4 127/5 138/21 139/7 141/6 141/13 141/16 142/2 142/13 146/10 146/11 149/8 172/10
worked [1] 5/16
workers [1] 8/21
working [27] 3/9 3/12 3/14 3/21 4/8 4/13 5/23 49/8 49/17 60/6 65/14 65/21 66/13 67/6 67/22 89/23 93/15 94/21 95/1 98/11 98/16 106/9 121/25 122/1 141/21 149/11 153/19
world [3] 39/10 64/23 75/14
worn [1] 82/10
worried [1] 20/2
worry [1] 149/4
worth [2] 53/10 80/3
would [95] 5/19 13/10 17/10 18/8 18/9 18/10 18/25 20/16 24/13 24/15 24/19 26/23 27/1 29/11 33/20 33/21 36/5 37/22 38/25 40/20 41/6 41/22 42/21 43/12 43/25 47/18 57/6 57/12 59/22 64/12 69/21 71/5 71/6 73/19 77/3 78/21 80/15 80/17 80/19 81/8 81/11 87/10 87/10 87/12 89/13 89/16 91/13 91/15 92/20 94/7 98/23 99/18 102/21 103/5 109/12 114/10 114/13 116/10 119/14 122/20 123/7 125/10 126/10 126/14 126/22 128/8 135/1 136/17 137/22 139/23 140/17 141/12 147/19 151/1 159/4 159/6 159/10 159/13 159/18 159/20 160/20 160/23 165/8 165/12 165/17 166/16 166/20 166/25 167/4 167/6 167/12 167/14 167/17 167/25 169/10
wouldn't [1] 91/24
write [6] 35/11 42/21 43/11 102/20 124/14 140/3
writes [2] 19/24 55/20
writing [14] 19/23 21/8 38/22 43/6 56/14 68/17 74/23 75/19 77/13 80/11 80/12 89/22 92/4 111/11
written [12] 1/24 34/13 34/22 36/17 41/22 55/23 66/1 110/23 132/21 139/19 139/21 170/5
wrong [2] 34/23 35/7
wrote [7] 43/3 58/14 90/13 127/23 128/22 132/16 164/4

X

X's [1] 36/23

Y

year [34] 14/9 14/9 15/8 19/12 22/11 23/4 25/10 27/18 39/22 40/4 40/8 50/5 60/8 60/9 62/7 77/16 91/6 91/11 93/22 94/2 94/8 99/4 105/8 110/11 116/18 123/12 123/25 139/1 142/9 142/17 143/14 143/20 143/22 167/6
years [16] 6/13 12/8 25/23 31/12 38/21 50/10 55/17 55/18 57/23 58/2 78/8 97/19 98/17 116/16 137/13 141/4
yes [28] 2/17 8/8 18/22 35/13 38/15 38/15 42/1 42/11 47/17 47/20 48/13 48/22 53/4 65/22 71/14 71/16 75/23 76/3 77/3 77/7 77/10 99/18 137/3 144/24 145/3 148/1 161/16 172/22
yesterday [5] 33/16 55/21 76/16 79/13 85/2
yet [5] 1/15 97/22 98/25 128/7 168/4

Y

York [1] 103/4
you [147] 2/15 6/1 8/5 9/11 9/11 11/12 11/20 11/20 11/25 12/19 19/12 19/13 19/14 19/15 22/9 23/3 23/5 23/10 23/15 23/16 23/19 24/4 24/24 28/25 29/7 33/25 35/21 36/4 36/5 36/22 42/8 42/19 43/6 43/11 48/7 48/11 48/12 53/8 54/10 54/24 57/21 58/11 59/8 63/13 64/15 68/16 70/16 71/6 72/17 73/9 74/16 74/17 74/18 74/18 75/21 77/10 82/9 85/1 86/12 87/14 89/14 89/22 90/16 91/16 92/7 92/10 92/11 94/12 97/1 97/5 97/7 97/9 100/1 101/9 102/20 103/4 108/6 109/12 109/23 109/24 111/8 113/18 117/19 118/3 120/9 122/19 123/5 126/3 126/4 126/5 126/7 126/18 128/7 128/16 131/2 131/12 131/20 132/9 132/21 132/22 134/2 135/14 135/17 135/18 136/2 136/11 136/15 136/17 137/6 137/18 137/21 137/21 137/25 139/14 141/14 144/8 144/21 145/10 145/20 146/2 149/14 149/16 149/17 154/9 155/1 155/5 156/5 156/6 157/6 160/9 160/16 160/25 165/2 169/24 170/7 170/9 170/10 170/13 172/9 172/22 172/23 172/24 172/25 173/1 173/2 173/3 173/4
you'd [1] 35/10
you'll [3] 49/22 126/25 130/13
you've [1] 137/25
young [6] 37/12 38/7 59/9 69/21 165/17 165/22
Youngest [1] 66/8
your [33] 6/7 22/17 22/18 22/19 23/1 23/20 23/22 24/4 26/8 36/6 36/22 53/2 80/15 82/10 92/7 103/13 108/8 109/8 109/12 125/25 126/7 126/13 126/15 131/10 135/13 136/11 136/25 137/22 140/3 157/7 164/11 169/3 173/1

Z

zoom [2] 111/6 149/25

F: